

## REQUEST FOR PROPOSAL

Title: To conduct Laboratory Testing Services for the Columbia University Miami Research Center in support of NIH funded multisite study of integrated HIV prevention & Hepatitis C care for people who inject drugs in Miami.

RFP Issue Date: February 6, 2020

RFP Due Date/Time: 5 PM, February 21st 2020

**Location:** Columbia University

**Procurement Services** 

615 West 131<sup>st</sup> Street, 3<sup>rd</sup> Floor New York, New York 10027

**Columbia RFP Representative(s):** 

Name: Michael Reich

Title: Director for Lab & Medical Sourcing

Phone: 1 212.854.2337

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Name: Iveth Gabriela Yanez Title: Project Coordinator

Dept. of Sociomedical Sciences

Columbia University Miami Research Center

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#### INFORMATION AND INSTRUCTIONS TO BIDDERS

### Section 1 General Information to Bidders

#### **Introduction:**

Subject to the terms and conditions set forth in this Request for Proposal, Columbia University is requesting sealed Bids for the following project:

Bid Name: To conduct Laboratory Testing Services for the Columbia University Miami

Research Center in support of NIH funded multisite study of integrated HIV

prevention & Hepatitis C care for people who inject drugs in Miami.

**Bid Deadline**: 5 PM, February 21<sup>st</sup> 2020

**Submission of Bids:** Michael Reich

Director for Lab & Medical Sourcing –

Procurement Services Columbia University

615 West 131st Street, 3rd Floor

New York, NY 10027

Bidders may submit their Bids in accordance with instructions provided in Section 2 on page 6, 'Submission of Bids' of this RFP document.

#### **Columbia Representative(s):**

Name: Michael Reich

Title: Director for Lab & Medical Sourcing

Phone: 212.854.2337

E-mail: mmr62@columbia.edu

Name: Iveth Gabriela Yanez
Title: Project Coordinator

Dept. of Sociomedical Sciences

Columbia University Miami Research Center

Phone: 1 786 703 9827

E-mail: iy2156@cumc.columbia.edu

#### **Definitions**

Except as otherwise specifically provided, definitions are set forth as follows:

*Columbia*— Refers to Columbia University.

**Request for Proposal (RFP)** - Refers to the document named Columbia's Request for Proposal for Breeding and Management of Miniature Swine Colony.

**Addenda** — Refers to the written or graphic instruments issued by the Columbia Representative prior to the Bid Deadline, which may modify or interpret the RFP by additions, deletions, clarifications, or corrections.

**Bidder** – Refers to the firm that is interested in and/or responds to the RFP.

**Bid** - Refers to all documents that the Bidder must submit to the Columbia Representative prior to the Bid Deadline.

**Bid Deadline** - Refers to the time and date indicated in the RFP as the latest date and time that a Bid will be accepted.

*Contract* – Refers to the final agreement reached between the successful Bidder and Columbia.

Contractor - The term Contractor shall mean the successful Bidder awarded the Contract.

**Subcontractor** — The term Subcontractor shall mean any individual, company, or corporation to whom the Contractor assigns any part of the Contract.

#### **Code of Conduct and Fair Competition**

It is the responsibility of the Bidder to notify the Columbia Representatives in writing of any possible conflict of interest as set forth below. Columbia will investigate the matter and determine if an actual conflict of interest exists.

A conflict of interest arises when a Columbia employee, officer or agent involved in the RFP process or Contract has a financial or any other interest in a Bidder. If a conflict of interest exists, the Bidder may not submit a Bid.

Columbia employees, officers and agents may neither solicit nor accept gratuities, favors, or anything of monetary value from Bidders, Contractors, or parties to sub-agreements. Any such actions must be reported to the Columbia Representatives immediately.

Columbia reserves the right to cancel the award if, in its sole discretion, it determines that any interest disclosed from any source could give the appearance of a conflict or cause speculation as to the objectivity of the program to be developed by the Bidder. Columbia's determination regarding any questions of conflict of interest shall be final.

#### **Compliance with Federal, State and Local Laws**

Bidder warrants in submitting a Bid and in the performance of an award as a result of the Bid, that Bidder has complied with, or will comply with, all applicable federal, state, University, and local laws, ordinances and all lawful orders, rules and regulations hereunder. The Bidder, by submitting the Bid or through performance that results from an award by Columbia, agrees not to discriminate against any employee or applicant based on an individual's race, color, religious creed, ancestry, national origin, age (except minors), sex, sexual orientation, marital status, medical condition (cancer-related) and disability, and otherwise as required or permitted by law. Bidder further agrees that any sub-contract will contain a provision requiring non-discrimination in employment as specified above. Any breach of this provision may be regarded as material breach of contract and cause for cancellation.

#### **Limitation of Liability**

Columbia makes no representations, warranties, or guarantees that the information contained herein is accurate, complete, timely, or that such information accurately represents the conditions that would be encountered in pursuing the work or at the site(s) of work now or in the future. The furnishing of such information by Columbia shall not create or be deemed to create any obligation or liability upon it for any reason whatsoever and each Bidder, by submitting its Bid, expressly agrees that it has not relied upon the foregoing information, and that it shall not hold Columbia liable or responsible therefore in any manner whatsoever. Accordingly, nothing contained herein and no representation, statement or promise, of Columbia, its directors, officers, agents, representatives, or employees, oral or in writing, shall impair or limit the effect of the warranties of the Bidder required by this Request for Bid and that it shall not hold Columbia liable or responsible therefore in any manner whatsoever.

Neither the Trustees of Columbia, nor any officer, agent, or employee thereof shall be charged personally with any liability by a Bidder or another or held liable to a Bidder or another under any term or provision of this RFP or any statements made herein or because of the submission or attempted submission of a response hereto or otherwise.

#### **Qualification of Bidder**

Bidder must possess the potential ability to perform successfully under the terms and conditions set forth in the RFP. Consideration shall be given to such matters as Bidder integrity; record of past performance; and financial and technical resources.

Columbia shall make such investigations as it deems necessary to determine the ability of a Bidder to provide the required services solicited under the RFP.

Columbia, at its sole discretion reserves the right to reject any Bid if the evidence submitted by, or investigation of, such Bidder fails to satisfy Columbia that said Bidder is properly qualified to carry out the obligations of the final Contract.

# Section 2 Submission of Bids

#### **Preparation of Bid**

By submission of its Bid, the Bidder agrees that the Bid is predicated upon the acceptance of all the terms and conditions stated in the Request for Proposal, unless specifically excluded by the Bidder in its Bid. Part or all of the RFP and the successful Bid may be incorporated into the Contract.

Each Bidder shall furnish the information and documents required by the RFP. Failure to submit all required information may deem a Bid as non-responsive. Columbia is exempt from Federal Excise Taxes and is also exempt from New York State and local sales or use taxes. All costs associated with the Contract must be stated in U.S currency. By submitting a Bid, Bidder certifies that the prices proposed have been arrived at independently, without consultation, communication or agreement for the purpose of restricting competition as to any matter relating to such prices with any other Bidder or competitor. Bidders are cautioned to write all descriptions and prices clearly so there is no doubt as to the intent and scope of the Bid.

A person who is legally authorized to bind Bidder to a Contract shall sign the Bid. A Bid submitted by an agent shall have a current Power of Attorney attached, which evidences the agent's authority to bind Bidder. The person signing the Bid shall initial erasures or other changes.

Unnecessarily elaborate Bids beyond what is sufficient to present a complete and effective Bid are not desired and may be construed as an indication of the Bidder's lack of cost consciousness. Elaborate artwork, expensive paper and bindings are neither necessary nor desired. The cost incurred for the preparation of the Bid is the sole responsibility of the Bidder. Columbia does not assume any liability for any pre-contract activity and/or cost incurred by Bidders responding to this RFP.

Bid information is not considered confidential or proprietary. Trade secrets and other proprietary data contained in Bids may be held confidential if the Bidder requests, in writing, that Columbia does so, and if Columbia agrees, in writing, to do so. Material considered confidential by the Bidder must be clearly identified. Such confidential/proprietary information must be easily separable from the non-confidential sections of the Bid. Marking the entire Bid as proprietary will be neither accepted nor honored. Notwithstanding any of the foregoing, Columbia reserves the right to use any of the ideas presented in any reply, Bid, discussion, negotiations or presentation related to the RFP.

If a Bidder intends to use subcontractor(s), the Bidder must identify in its Bid the names of the subcontractors and the portions of the work the subcontractors will perform. Upon request qualifications of subcontractors shall be provided to Columbia.

#### **Communications Regarding the RFP**

Requests for clarification and interpretations of the RFP must be made in writing via email by 2/11/2020. All questions regarding the RFP shall be directed to the both Columbia Representatives in writing by e-mail. Two types of questions generally arise. One may be answered by directing the questioner to a specific section of the RFP. Other questions may be more complex and may require a written amendment to the RFP. The Columbia Representatives will make that decision.

The Columbia Representatives shall make clarifications, interpretations, corrections, and changes to the RFP in

writing through email or by written Addenda as specified below. Questions will not be answered and clarification will not be given after February 14<sup>th</sup> 2020.

#### Addenda to RFP

Addenda to the RFP will be issued in writing, will be communicated to all prospective Bidders by e-mail, and shall become part of the RFP. If the RFP is amended, all terms and conditions that are not modified by the Addenda remain unchanged and in effect as written. If an addendum is issued after Bids have been received and/or after a short list has been developed, the addendum may be provided only to those who submitted Bids or only to those on the short list, in the sole discretion of Columbia.

Each Bidder shall be responsible for making sure it has received all issued Addenda prior to submitting a Bid. Addenda may be issued by Columbia through February 17<sup>th</sup> 2020.

Columbia reserves the right to change the RFP schedule and to issue addenda. Columbia also reserves the right to cancel, reissue, or to make corrections or amendments to the RFP due to errors or changes identified by Columbia or suggested by a Bidder, and to otherwise modify the terms of the RFP at any time in its sole discretion.

#### **Submission of Bids**

Bids are to be received in the designated office on or before the due date and time specified as the Bid Deadline in the RFP. **Oral, telephone or facsimile Bids will not be considered**. If a Bid is to be sent by email as instructed in this section, please send to RFP Representative – Michael Reich at mmr62@columbia.edu.

It is also required for physical bid proposals to be provided, bids shall be submitted in a sealed envelope or package as follows:

- 1 Addressed to the address specified on the cover page of this RFP,
- 2 Show the Bid Name, "RFP For Breeding and Management of Miniature Swine Colony",
- 3 Give the Bidder's name, primary contacts address, and
- 4 Show the date and time of the Bid Deadline as specified in this RFP

Please be sure to include two hardcopies and one electronic copy of the Bid Proposal.

Columbia, or any of Columbia's representatives, officers, or employees, will not be held responsible for the pre-opening of, post-opening of, or the failure to open a Bid not properly addressed, delivered and/or identified.

#### **Alternate or Substitute Bids**

Bidders may submit more than one Bid. Alternate or substitute Bids must comply with the terms and conditions of the RFP and must contain all required documents as specified in the RFP.

Columbia is seeking Bids that meet its basic requirements as outlined in the Scope of Work. If more than one method of meeting these requirements is proposed, each should be labeled primary, secondary, etc., submitted separately, and they will be evaluated in the specific priorities.

#### Late Submissions, Modifications, and Withdrawals of Bids

<u>Late Bids</u>: Bids received after the specified Bid Deadline may not be considered and may be returned to the Bidder unopened at Columbia's sole discretion.

<u>Bid Modifications:</u> Prior to the Bid Deadline, a submitted Bid may be modified by written notice, signed by a duly authorized person on behalf of the Bidder, addressed to the Columbia Representative.

Bid Modifications must contain all required documents as specified in the RFP. Failure to submit all required information may deem the Bid Modification as non-compliant and the contents of the Bid Modification may not be considered.

A previously submitted Bid will not be returned, unless a written request, signed by a duly authorized person, from the Bidding Company is received by the Columbia Representative requesting such return.

<u>Bid Withdrawal Notifications:</u> Prior to the Bid Deadline, a submitted Bid may be withdrawn by written notice to the Columbia Representative up until the Bid Deadline. Written requests to withdraw must be signed by a duly authorized person on behalf of the Bidder and shall not reveal the amount of the Bid. Bids may not be modified, or withdrawn after the Bid Deadline.

A withdrawn Bid may be resubmitted prior to the Bid Deadline. All resubmitted Bids must fully comply with the RFP. Columbia will only consider the latest version of the Bid.

#### Section 3 Evaluation of Bids

#### **Opening of Bids**:

The assigned Columbia Representatives will not accept Bids after the specified date and time. Bid services and pricing will not be publicly announced. Bids will be reviewed and evaluated by Columbia. At any time, and from time to time after the opening of the Bids, Columbia may give oral or written notice to one or more Bidders to furnish additional information relating to its Bid and/or qualifications to perform the services contained in the RFP, or to meet with designated representatives of Columbia. The giving of such notice shall not be construed as an acceptance of a Bidder's Proposal.

All materials submitted in response to this RFP become the property of Columbia. Selection or rejection of a response does not affect this right. All copyright of materials produced under any contract or subcontract awarded as a result of this RFP shall be retained by Columbia. All forms of documents and data generated as a result of this contract are owned by and shall be delivered to Columbia at the direction of the Columbia Representative. During the period of performance, the information may not be disclosed by the Bidder to third parties, except as expressly provided in the Contract, without the written permission of the Executive Director of Purchasing.

#### **Postponement of Bid Opening**

If an emergency or unanticipated event interrupts normal University processes to cause the postponement of the scheduled Bid opening or the issuance of an addenda, the Columbia Representative will issue, in writing, to all Bidders, the new timeline and process.

#### **Bid Evaluation and Selection Criteria**

#### **Evaluation Criteria**

Columbia may use a variety of procedures and techniques in evaluating Bids and Bidders, including, but not limited to, creating a short list of Bidders, using upset levels, banding, comparative pairing, and price conversion techniques, requesting Best and Final Offers, conducting discussions, oral interviews and presentations, site visits, and negotiations, checking references, determining financial capability, and performing reevaluations of Bids as necessary. Through use of any procedure or technique, Columbia may limit the number of Bids to one or more that it will continue to consider. Columbia reserves the right to reject any Bid that does not meet prerequisites or minimum requirements or which scores below average on any of the criteria.

This RFP is being requested for services that are funded through the use of Sponsored Projects funds, the primary evaluation criteria that will be used to determine the successful bidder are:

- The professional and technical ability/capacity to provide the desired services. This shall include experience, turnaround time, specimen handling service levels including reliability, accuracy of testing results and reputation.
- The overall cost to Columbia.
- Results reporting.

#### Selection

Columbia reserves the right to make an award without further discussion of the Bids submitted; there may be no best and final offer procedure. Interviews and negotiations may be conducted with one or more of the Bidders, but there shall be no obligation to receive further information from any Bidder. Therefore each initial offer should contain the Bidder's best and most comprehensive terms from a cost, price, service, and technical standpoint.

Columbia may consult references familiar with the Bidder regarding its prior operations and projects, financial resources, regulatory record, reputation, performance, or other relevant matters. Submission of a Bid shall constitute permission for Columbia to make such inquiries and authorization to third parties to respond thereto. Columbia may elect to initiate contract negotiations with one or more Bidders including negotiation of costs/price(s) and any other issues or terms and conditions, including modifying any requirement in the RFP. The option of whether or not to initiate contract negotiations rests solely with Columbia.

No Bidder shall have any claims against Columbia arising from such negotiations. The Bidders will be responsible for their travel and per diem expenses, required for any presentations, discussions, and/or negotiations.

Columbia reserves the right to award the Contract to a contractor other than the Bidder presenting the lowest price. The Contract resulting from this solicitation will be awarded to the Bidder(s) whose Bid(s) Columbia believes will be the most advantageous to Columbia overall. The release of the RFP does not compel Columbia to purchase or to make an award. Columbia shall not be obligated in any manner to any Bidder whatsoever until a written Contract has been duly executed relating to an approved Bid and Purchase Order has been issued. Columbia reserves the right to award multiple contracts for the products, work and/or services that are the subject matter of this Bid and Bidder(s) are hereby given notice that they may not be Columbia's only Contractor or Bidder for such products, work and/or services.

As a result of the selection of a Bidder to provide the respective services to Columbia, Columbia is neither endorsing nor suggesting that the Bidder's services are the best or only solution. The Bidder agrees to make no reference to Columbia in any literature, promotional material, brochures, sales presentation or the like without the express written consent of Columbia's authorized Office of Communications.

The Bidder will be expected to enter into a Contract with Columbia for the performance of the laboratory services which are the subject matter of this RFP. Columbia University has provided a sample standard service agreement for review. Bidder may submit its own standard contract terms and conditions as a response to this RFP which are subject to review and revision. If a Bidder objects to any of the provisions of Columbia's standard contract, it must identify in the Bid any clauses which are unacceptable and the reasons or problems and propose alternatives. The foregoing should not be interpreted to prohibit either party from proposing additional contract terms and conditions during negotiation of the final contract.

#### **Rejection of Bids**

Columbia has the right to reject any and all Bids for any reason.

#### **Planned Timeline**

February 6<sup>th</sup> Request for Proposals Posting

February 11<sup>th</sup> Deadline for Questions & Requests for Clarifications

February 14<sup>th</sup>. Deadline for Responses by Columbia

February 21<sup>st</sup> Proposals Due Date

TBD Notification of Selections/Negotiation Agreement to Selected Vendor

TBD Agreement Finalize & Commence Implementation

Note to bidders: It is the intent of Columbia University to move forward with an award and implementation of services as soon as reasonably practical, subject to final agreement negotiations.

#### **Notification of Award**

The Columbia Representative will issue "Notification of Award" letter(s) once a selection has been made and an agreement has been entered into.

#### **Deadline**

Proposals should be submitted by February 21<sup>st</sup> 2020. Vendor interviews, vetting and selection will occur in the following month.

#### Formatting guidelines:

All proposals must provide a response to all of the items requested. All proposals should be submitted as a single pdf document containing components listed.

Questions must be addressed to: Iveth G. Yanez <u>iy2156@cumc.columbia.edu</u> and <u>mmr62@columbia.edu</u>

# Section 4 University Background Information

#### **General Information**

#### **Institute & Project Background Information:**

The Miami Research Center is a satellite center of the Department of Sociomedical Sciences at the Mailman School of Public Health. Since its inception in 2012, The Miami Center has focused on maintaining and growing Miami-based research programs directed towards the development of innovative strategies to increase the uptake of HIV testing, linkage, retention, and re-engagement in care among vulnerable populations.

Created by Dr. Lisa Rosen Metsch, Dean of Columbia School of General Studies, the Center's research team is locally directed by a Miami-based Columbia faculty member, Dr. Lauren Gooden. In addition, the Center is comprised of various project directors, study coordinators and numerous field staff, including outreach workers/recruiters, interventionists, and research assistants. Together, the faculty and staff based at the Miami Research Center implement a large research portfolio of multi-site and single site clinical trials and other longitudinal studies.

Columbia University Miami Research Center is the recipient of a federal award funded by the NIH titled: A Multisite Multi-Setting RCT of Integrated HIV Prevention and HCV Care for PWID (Peopled who inject drugs). The study requires that Columbia University Miami Research Center recruit study participants and collect urine and blood specimens which will be sent to selected service provider for laboratory analysis.

#### **Project Background Information & Objectives:**

The M2HepPrEP (A Multi-site Multi-Setting RCT of Integrated HIV Prevention and HCV Care for PWID) study is a randomized hybrid effectiveness-implementation trial (n=500) to evaluate two implementation strategies for PrEP and hepatitis C virus (HCV) care integration among people who inject drugs (PWID): on-site integrated care (PrEP initiation and HCV treatment) vs. off-site referral with patient navigation to specialized care.

HIV-negative PWID will be recruited from two venues—opioid substitution therapy (OST) venues and syringe exchange programs (SEPs)—within two North American cities—Miami and Montréal. The cities provide variability in background health access (Montreal-High Services/Low Barriers versus Miami-Low Services/High Barriers); venues provide variability in resources (opiate treatment programs (OTPs)-High Resources versus SEPs-Low Resource). There are two overall aims: 1) To determine if integrated PrEP and HCV treatment offered on-site, in treatment and harm reduction settings, result in higher rates of a) sustained PrEP adherence and/or b) HCV cure (primary outcomes), compared to an off-site referral with patient navigation, and to c) test the contributions of local environment and venue on primary outcomes, and 2) To evaluate a) the health care utilization impact and the relative resource use of the on-site integrated care approach compared to the referral with patient navigator approach and b) the health care resources required to scale up these intervention approaches in the local environments and settings.

Once participants are randomized, the study will involve up to 18 visits over a period of about 18 months. Participants will: 1) take part in interviews; 2) provide blood and urine samples that the research team will assess for HIV, HCV, sexually transmitted infections, liver function drug/alcohol use and pregnancy (as applicable); 3) sign release forms to permit medical records abstraction; and 4) receive adherence counseling and/or help from a patient navigator with getting the participant to a clinic for PrEP and HCV treatment (as applicable).

#### **Service Provider Requirements:**

Prospective Bidders must be capable of offering the full range of laboratory tests in Miami, FL. Bidder must be able to operate in accordance with CLIA – based protocols. Compliance and adherence with all applicable federal, state and local statutes and regulations, governmental guidelines including but not limited to HIPAA regulations as updated from time to time. Bidders must provide subject de-identification requirements that Columbia is required to adhere to when submitting samples for analysis.

# Section 5 Bidder's Declaration

This Bid is in response to Columbia's request for a Bid ("RFP") for Laboratory Services pursuant to a federally funded award.

This Bid consists of:

Information & Instructions for Bidders

Bid Part I - Bidder's Declaration

Bid Part II - Bidder Questionnaire

Bid Part III - Scope of Work ("SOW")

Bid Part IV - Exceptions to Columbia Terms & Conditions and

Appendix A Financial Proposal

Bidder agrees to perform in accordance with all provisions of the RFP documents and any addenda thereto, except as may be specifically stated in this Bid, at the prices set forth herein.

Bidder agrees that this Bid is a firm offer to Columbia which cannot be withdrawn for 120 calendar days from and after the Bid due date.

Bidder certifies that it has thoroughly examined and fully understands all of the provisions of the RFP and the conditions of the contract documents attached thereto, as well as any addenda issued prior to the due date; that it has carefully reviewed and fully supports the accuracy of its Bid; has satisfied itself as to the nature and location of all work, the technical, general, and local conditions to be encountered in the performance of any work, the requirements of the Contract and all other matters which may in any way affect performance or the cost thereof; and that Columbia shall not be responsible for any errors or omissions on the part of the undersigned in preparing this Bid.

If awarded a Contract, Bidder agrees to execute the Contract and deliver it to Columbia within 15 calendar days, of such award, along with any required certificates of insurance.

Authorized Signatory	Title
Company Name	Date
Company Add	ress
Telephone Number	Federal Taxpayer I.D. Number
Email Address	DUNS Number

#### Section 6 Bidder's Questionnaire

#### **A. Bidder Business Structure**

- 1. Provide your company's name and address, and the primary RFP contact's name, phone number, e-mail address and fax number.
- 2. Please provide the primary locations of your company's offices in North America. Indicate which laboratories would service this account. Please provide full details for the respective location.
- 3. Please list your firm's other lines of business and the approximate contributions of each business to your organization's total revenue. If you are an affiliate or subsidiary of an organization, what percentage of the parent firm's total revenue does your subsidiary or affiliate generate?
- 4. Is Bidder incorporated? If so, in what state and as what type of corporation?

#### **B. Bidder Financial Information**

- 1. Please provide your Dun and Bradstreet (DUNS) Number, if any.
- 2. Please provide your current DUNS rating:
- 3. Please provide your Standard and Poor's rating:
- 4. Bidder must attach its most recent annual report or certified financial statement as well as most recent SEC 10K filing.
- 5. Please provide your previous year's revenues.
- 6. What percentage of Bidder's annual revenues would any contract resulting from this Bid represent?
- 7. Please describe any subcontractor relationships that would be involved in the support of any Columbia contract. (use of any subcontractor requires Columbia approval in advance. Failure to do so may result in termination of contract.)

#### **C.** Business Information

- 1. List any material regulatory action, claim asserted or threatened against Bidder that may have a significantly adverse effect on Bidder or adversely affect Bidder's ability to provide the goods or services required by this RFP.
- 2. List any business issue currently confronted by Bidder that may have a significantly adverse effect on Bidder or adversely affect Bidder's ability to provide the goods or services required by this RFP.
- 3. List 3 of your customers using the service covered by this Bid similar in size, industry sector, and geographical presence to Columbia. Please provide:

- Customer name and address
- Customer employee size
- Contact names and telephones (business and technical)
- Brief description of the service provided
- How long has Customer been using Bidder to provide services?
- 5. List information regarding 2 of your customers (must currently be operational) previously using Bidder to provide services that **no** longer is using Bidder to do so. Please provide:
  - Customer names and addresses
  - Describe service provided by Bidder
  - Contact names and telephones
  - How long were these Customers using Bidder to provide the service?
  - Why did these Customers cease their business relationship with Bidder?
- 5. Describe other current products/services Bidder has provided to Columbia (if applicable).
- 6. Describe any existing or pending contracts between Bidder and Columbia. Please exclude contracts pending associated with this RFP initiative.
- 7. List the name and location of primary individual(s) who would be responsible for our account and provide brief biographies including titles, functions, academic credentials, and relevant experience. Include the role of each consultant for this assignment, the role of back-up personnel and how many clients are assigned to each person named above?
- 8. Has your company or any individual in your company ever been debarred, suspended or presented on the OFAC list relevant to any activities contemplated with the US Federal Government?

#### **D. Bidder Diversity**

It is the policy of Columbia to promote and increase the participation of minority-owned business enterprises ("MBE's" or "MWL's") as suppliers and second-tier providers. A MWBE is defined as a business enterprise more than 50% of which is owned by women, disadvantaged or minorities. To the extent practicable, maximum opportunity shall be given to qualified MBEs to participate as suppliers and contractors to Columbia. All qualified suppliers are provided equal opportunity to compete and participate in the Columbia's procurement process subject to all the established purchasing policies and procedures.

- 1. Please indicate your MWBE status.
- 2. Are the owner(s) of Bidder United States citizens?
- 3. Has Bidder ever been certified as an MBE by any agency? If so, please provide a copy of the certification.
- 4. Please provide the name(s) and phone numbers of any dedicated Bidder personnel who deal with MBE issues.
- 5. Please discuss Bidder's own MBE program, and if Bidder is not a MBE itself, describe Bidder's ability to provide any "second-tier" reporting to Columbia. Second-tier reporting provides details of Bidder's expenditures, by ownership category, with MBE's related to any contract.

0.	Zip Codes –	ousiness operates in t	ne ronowing to	cutions.	
	<ul> <li>10025 - 10027</li> <li>10029 - 10040</li> <li>10451</li> <li>10454 - 10455</li> <li>10474</li> </ul>				
	New York Boroughs	_			
	Brooklyn	Queens	Bronx	Staten Island	Manhattan
7. who	en possible:	mitted to the hiring of o	•		ve mentioned local areas

Does your proposal address the hiring of local residents?

6. Please indicate if your business operates in the following locations:

Has your company engaged local talent in any previous engagements (through any contract whether or not with Columbia)? If please describe. so.

#### MINORITY AND LOCAL PLAN

What operations, if any, are currently located in the New York Empowerment Zone (NYEZ)? Can you present options how this area of the Columbia community can be integrated into this program?

See below for zip codes that comprise this referenced area.

- We encourage bidders to explore potential partnering or subcontracting arrangements with MWL vendors to maximize Minority & Local participation. Please detail any plans you may have with regard to creative partnering or subcontracting with MWL vendors.

#### NYEZ zip codes:

- 10025 10027
- 10029 10040
- 10451
- 10454
- 10455
- 10474

Columbia attaches great importance to the bidder's ability to utilize MWL (Minority, Women, and or Locally) owned businesses in the performance of this contract. This can be accomplished by, 2<sup>nd</sup> Tier MWL vendor usage, opening of a facility within the New York Empowerment Zone (NYEZ) region, maximization of minority, women owned and local subcontract participation and innovation in recruitment and training of employees through community work force development.

What operations, if any, are currently located in the New York City area (includes 5 boroughs)? Can you present

options how this area can be integrated into this program?

# Scope of Work (SOW)

The Columbia University Miami Research Center (Institution) is requesting bids to provide clinical laboratory services pursuant to a federal award. Project Title: A multi-site Multi-Setting RCT of Integrated HIV Prevention and HCV Care for PWID. Grant Number 5R01DA045713-03 Principal Investigator for Columbia Lisa R Metsch (PHD).

The purpose of the study is to provide for randomized control trial of integrated HIV prevention and Hepatitis C care for people who inject drugs in Montreal Canada and Miami Florida. This SOW covers Miami based activities only. The vendor selected pursuant to this RFP shall be responsible to assist Institution with specific laboratory testing and processing of biological specimens. The list of specific tests is attached as Appendix B. The successful bidder will perform testing at one of its Miami area clinical laboratories and provide test results to Institution in accordance with CLIA based protocols.

Institution will be responsible for recruitment of study participants. It is anticipated initially approximately 360 participants will be recruited and screened. From these initial 360 interviewed and screened participants 250 are expected to be recruited of which approximately 200 are anticipated to complete the study trial.

Once participants are randomized, the study will involve up to 18 visits over a period of about 18 months. Participants will: 1) take part in interviews; 2) provide blood and urine samples that the research team will assess for HIV, HCV, sexually transmitted infections, liver function drug/alcohol use and pregnancy (as applicable); 3) sign release forms to permit medical records abstraction; and 4) receive adherence counseling and/or help from a patient navigator with getting the participant to a clinic for PrEP and HCV treatment (as applicable).

Vendor will be responsible to process specimens collected by Institution, deliver timely reports (Please specify guaranteed turnaround time), store specimen samples, provide pickup services, supplies for specimen collection and courier services as needed. Vendor shall provide proposed pricing and SLA's for standard associated services for duration of the trial. Whenever possible please bundle testing to achieve cost savings.

## **NO-BID FORM**

RFP TI	TLE:	
RFP#:		
Bidders	choosing no	t to bid are requested to complete the portion of the form below:
It is our	intention no	ot to submit a proposal for the following reason(s):
-		we do not provide the requested services
-		we do not provide the requested goods
-		we are unable to meet the minimum qualifications
-		due to other engagements we would be unable to support this proposal
-		due to a conflict of interest we are unable to submit a proposal
-		other (please provide additional rationale below)
Signatu	re:	
Name:		
Title:		

## CONTRACT ACKNOWLEDMENT

<b>DATE:</b>	February 6, 2020	
FROM:	Vendor Name Address	
то:	Columbia University in	the City of New York
		RE: PROPOSAL/BID DESCRIPTION  Project Description
		Quotation #
	are ultimately awarded the	fully read the Appendix "A", (agreement type) enclosed in the package. We acknowledge contract we will promptly execute an agreement containing substantially similar terms
	ote any contract exception not have any exceptions.)	s in the space below or provide an attachment with appropriate signature. Type NONE
Note Exc	eptions:	
Signature Name:	2:	
Title:		

# APPENDIX A Columbia University Service Provider Agreement

Service Provider Agreement ("Agreement") dated as of	, 20	(the "Effective Date")	between The
Trustees of Columbia University in the City of New York (	'Columbia") and		
("Service F	Provider").		

- 1. <u>Scope</u>. Service Provider agrees to perform the services described in Attachment 1 (the "Services").
- 2. <u>Payments</u>. Conditioned upon Service Provider's performance of the Services in accordance with this Agreement, Columbia will pay Service Provider the amounts specified in Attachment 1 (the "Statement of Work"). The payments specified in Attachment 1 represent Columbia's total financial commitment to Service Provider for all Services and deliverables, and other obligations under this Agreement.

#### 3. Performance of Services.

- (a) Service Provider will perform the Services in a timely manner and in accordance with any project schedule set forth in Attachment 1. The parties agree that "time is of the essence" with respect to Service Provider's performance.
- (b) Service Provider will assign qualified and experienced personnel to perform the Services. Where Attachment 1 identifies specific Service Provider personnel, these individuals will remain assigned to provide the Services throughout the term of this Agreement, in accordance with their roles and responsibilities identified in Attachment 1, unless otherwise approved in writing by Columbia. However, if Columbia objects to the manner of performance of any Service Provider personnel (including any third party contractors or agents of Service Provider), Service Provider will promptly take all necessary actions to rectify the objections, including, if requested by Columbia, the prompt removal of the individual from the provision of Services to Columbia. If it becomes necessary to replace any personnel, Service Provider will provide as a replacement a person with equivalent or better qualifications, as approved by Columbia (such approval not to be unreasonably withheld).
- (c) Columbia will have a reasonable opportunity (not to exceed 30 days, unless otherwise specified in Attachment 1) to review all deliverables or Services provided to Columbia under this Agreement. If Columbia informs Service Provider of a deficiency in the deliverables or Services, Service Provider will promptly make corrections and re-submit them to Columbia for review and approval. Service Provider will not charge Columbia for the time and expense in making corrections to deliverables that fail to comply with the requirements of this Agreement. If Service Provider is not able to timely make all appropriate corrections, Columbia may elect to terminate the applicable Statement of Work(s), in which event Service Provider will promptly refund any amounts previously paid by Columbia for work not performed in accordance with this Agreement. Nothing in this clause (c) will excuse Service Provider from meeting any delivery or project schedule set forth in Attachment 1.
- (d) Service Provider will provide timely and complete status and other reasonable reports to Columbia at least once each month or as otherwise required by Attachment 1. Status reports will identify anticipated or actual project delays or issues in reasonable detail. If Service Provider believes that Columbia is failing to perform any activity or obligation that will delay or interfere with Service Provider's performance of this Agreement, Service Provider will promptly notify Columbia's Project Manager in writing, and will cooperate with Columbia's efforts to resolve the matter. Columbia's failure to perform any activity or obligation will not excuse Service Provider's delay or nonperformance, unless Service Provider provides timely notice to Columbia in accordance with this Agreement.

#### 4. Warranties.

- (a) Each of Service Provider and Columbia warrants that it has the requisite power and authority to enter into and perform its obligations under this Agreement. Service Provider warrants that it is not debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any governmental department or agency.
- (b) Service Provider warrants that it will perform the Services (i) in a diligent and highly professional manner, (ii) in accordance with applicable law; and (iii) through experienced individuals qualified to perform the Services. Service Provider will obtain all required governmental and third-party licenses, approvals, and permits appropriate for the provision of Services and deliverables.
- (c) Service Provider warrants that all deliverables will be developed in accordance with the quality standards of the applicable industry, and will meet in all respects the requirements set forth in Attachment 1. Service Provider further warrants that the Services and deliverables will not infringe or misappropriate the rights of any third party, and that Service Provider has all power and authority to convey ownership of the Services and deliverables to Columbia in accordance with this Agreement.

#### 5. Confidentiality.

- (a) Service Provider acknowledges that in the course of performing its responsibilities under this Agreement, Service Provider may be exposed to or acquire information that is proprietary or confidential to Columbia University and/or its affiliates. For purposes of this Agreement, such information ("Confidential Information") shall include all information, written or oral, relating to the business, operations, services, facilities, processes, methodologies, technologies, intellectual property, research and development, employees, patients, faculty and students, other consultants and authorised agents of Columbia University, and/or its affiliates.
- (b) Service Provider agrees to hold the Confidential Information in strict confidence and not to disclose the Confidential Information to third parties or use Confidential Information for any purposes whatsoever, other than for the performance of Service Provider's obligations hereunder, without the express written permission of Columbia University. Without limiting the foregoing, Service Provider shall be permitted to disclose Confidential Information only to its officers and employees who have an absolute need to know such Confidential Information in order to fulfil Service Provider's obligations to Columbia University hereunder and who are informed of and agree to be bound by the confidentiality obligations of this Agreement. Service Provider shall use reasonable efforts to assist Columbia University in identifying and preventing any unauthorized use or disclosure of any Confidential Information. Without limiting the foregoing or liability therefor, Service Provider shall immediately advise Columbia University in the event that it learns or has reason to believe that any person who has had access to Confidential Information has violated or intends to violate the terms of this Agreement, and will reasonably cooperate in seeking injunctive relief against such person.
- (c) All Confidential Information is and shall remain the sole property of Columbia University. Service Provider shall not gain any interest or rights in or to the Confidential Information by virtue of its disclosure to Service Provider for the limited purposes contemplated hereunder.
- (d) Notwithstanding the foregoing, the confidentiality obligations shall not extend to information that: (i) as of the time of its disclosure or thereafter becomes available to the public through a source other than Service Provider, (ii) was rightfully known to Service Provider as of the time of its disclosure, (iii) is rightfully learned by Service Provider from a third party not under a confidentiality obligation to Columbia University, or, (iv) is required to be disclosed pursuant to a subpoena, court order, or government authority, whereupon Service Provider shall provide prompt written notice to Columbia University prior to such disclosure, so that Columbia University may seek a protective order or other appropriate remedy.
  - (e) Promptly upon the conclusion of the Services, the delivery of final Deliverables or at such earlier time as

Columbia University may direct, Service Provider shall return to Columbia University all Confidential Information in its possession, including all copies thereof. Upon request Service Provider shall certify to Columbia University in writing that all Confidential Information has been returned.

#### 6. Ownership Rights.

- (a) All deliverables to be provided under this Agreement, and any invention, improvement, discovery, or innovation (whether or not patentable) made, conceived or actually reduced to practice by Service Provider in the performance of Services hereunder, (collectively the "Work Product") will be owned exclusively by Columbia, including all proprietary and intellectual property rights therein. To the fullest extent permissible under law, the Work Product will be a "work made for hire" for the University. To the extent not automatically vested in Columbia, Service Provider hereby assigns to Columbia all right, title and interest in and to the Work Product, including, without limitation, copyright, patent, and trade secret rights. Upon Columbia's request, Service Provider will execute any additional documents necessary for Columbia to perfect its ownership rights.
- (b) Notwithstanding the foregoing, Service Provider will retain ownership of its pre-existing and proprietary materials and other intellectual property that may be incorporated into the Work Product, provided that Service Provider will inform Columbia in writing before incorporating any pre-existing material or pre-existing intellectual property into the Work Product. Service Provider hereby grants Columbia a perpetual, irrevocable, royalty-free, worldwide right and license (with the right to sublicense) to freely use, make, have made, reproduce, disseminate, display, perform, and create derivative works based on such pre-existing materials and intellectual property as may be incorporated into the Work Product or otherwise provided to Columbia in the course of performing the Services.

#### 7. Indemnity.

- (a) To the fullest extent permitted by law, Service Provider will indemnify, hold harmless and defend Columbia, its trustees, officers, faculty, students, agents, and employees against any and all damages, suits, actions, claims, liabilities, losses, judgments, costs and expenses arising out of or relating to (i) any personal or bodily injury (including death) or property damage caused by Service Provider's negligent, willful, or unlawful acts or omissions or breach of this Agreement, (ii) breach of Service Provider's confidentiality obligations, or (iii) an infringement or misappropriation of any third party intellectual property or proprietary rights (including, without limitation, trademark, trade secret, copyright or patent) by the Services or Work Product.
- (b) Columbia will provide prompt written notice to Service Provider of any claim that Service Provider is obligated to indemnify under this Agreement. Service Provider will be permitted to control the defense of the claim and any related settlement negotiations, and Columbia will cooperate (at Service Provider's expense) with the defense and settlement of the claim. In seeking to settle a claim, Service Provider may not purport to accept or expose Columbia to any liability, or admit to any fault, unless approved in writing in advance by an authorized representative of Columbia. Columbia will have the right, at its option and expense, to participate in the defense of any suit or proceeding through counsel of its own choosing.

#### 8. Disputes.

- (a) The parties will make good faith efforts to resolve any dispute concerning this Agreement prior to commencing litigation.
- (b) Columbia will not be deemed in breach of this Agreement for withholding any portion of payment that Columbia is disputing in good faith. Columbia will, however, make prompt payment of any portion of an amount not under dispute.
- (c) The laws of the State of New York will govern all rights, duties, and obligations arising from or relating in any manner to this Agreement, without regard to conflict of laws principles. Any and all claims arising from or

relating to this Agreement will be heard either in United States or New York State courts located in County of New York.	n the City and
9. <u>Use of Name</u> . Service Provider will not use the name, insignia, or symbols of Columbia, its factorization departments, or any variations or combination thereof, or the name of any trustee, faculty member or student of Columbia for any purpose whatsoever without Columbia's prior written consent.	culties or r, other employee,
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#### 10. Term and Termination.

- (a) The term of this Agreement is from \_\_\_\_\_\_, 20\_\_\_ to \_\_\_\_\_\_, 20\_\_\_, unless otherwise terminated in accordance with this Section. The Statement of Work will begin on the Effective Date and will end when Service Provider and Columbia have completed their obligations there under, unless otherwise stated in the Statement of Work.
- (b) Columbia may terminate this Agreement in whole or in part at any time without cause upon at least 15 days written notice to Service Provider. If this Agreement is a subcontract (with Columbia being the contractor to another party, and Service Provider being Columbia's subcontractor), then Columbia may immediately terminate this Agreement upon written notice to Service Provider if the prime contract is terminated for any reason.
- (c) Columbia may terminate this Agreement for Service Provider's breach upon at least 10 days written notice to Service Provider, unless during such notice period Service Provider fully cures the breach to Columbia's reasonable satisfaction.
- (d) Service Provider may terminate this Agreement for Columbia's breach for failure to pay any amounts then due upon at least 30 days written notice to Columbia, unless during such notice period Columbia fully cures the breach.
- (e) If Columbia terminates this Agreement without cause, Columbia will promptly pay Service Provider for its Services performed through the effective date of termination, in accordance with the terms of this Agreement.
- (f) In the event of any termination, or at any time upon Columbia's request, Service Provider will: (i) immediately return to Columbia any Columbia proprietary materials and information in Service Provider's possession or control, including without limitation all Columbia Confidential Information and any deliverables then under development; and (ii) at Columbia's request, cooperate with Columbia in the transition of the work performed under this Agreement to Columbia or its designee.
- (g) Any provisions of this Agreement (including, but not limited to, confidentiality and indemnity obligations) that by their nature extend beyond termination will remain in effect in accordance with their terms.

#### 11. Insurance.

- (a) Service Provider will maintain, at its own cost and expense, the following types and amounts of insurance with insurers rated "A" "VII" or better by A.M. Best and licensed in the State of New York:
  - 1) Commercial General Liability insurance, written on an occurrence basis including, but not limited to, coverage for contractual liability, products and completed operations, personal injury, bodily injury and broad form property damage liabilities with liability limits not less than \$1,000,000 per occurrence and annual aggregate. Products and completed operations insurance shall be maintained for 3 years following termination of this Agreement.
    - 2) When working on-site at Columbia facilities or at Columbia sponsored events.
  - (i) Workers' Compensation and Employers Liability insurance, covering each employee of Service Provider engaged in the performance of work under this Agreement, with minimum limits of liability in accordance with applicable state law in the case of Workers' Compensation insurance, and with not less than the following limits of liability in the case of Employers Liability insurance: Workers' Compensation Coverage A Statutory; Employers Liability -Coverage B- Each Accident \$1,000,000; Policy Limit \$1,000,000; Each Employee by Disease \$1,000,000.
    - (ii) Automobile Liability insurance covering all owned, non-owned and hired vehicles used in

connection with the performance of work under this Agreement, with a combined single limit of liability for bodily injury and property damage of not less than \$2,000,000 per occurrence.

- 3) Each of the policies required by subsections (1) and (2.ii) above shall provide that the insurance company pay the costs of defense (including attorneys' fees) of any suit or proceeding against Columbia University or its trustees, officers, agents, or employees, alleging any omission or act relating to this Agreement, and seeking damages on account thereof, even if such suit is groundless, false or fraudulent. These insurances shall be primary and shall be written to cover claims incurred, discovered, manifested or made during or after the expiration of this Agreement. Insurance procured by Service Provider shall not reduce or limit Service Provider's obligation to indemnify and defend Columbia University or Service Provider's liabilities for claims made or suits brought which result from or are in connection with the performance of this Agreement. Any insurance Columbia University may purchase shall be excess and non-contributory.
- (b) Prior to commencement of the work, Service Provider will deliver certificates of insurance to the University providing evidence of the coverage required above. Each certificate of insurance shall provide for a 30-day written notice of cancellation or material change and, with the exception of Workers' Compensation and Employers Liability Insurance, shall name The Trustees of Columbia University in the City of New York, its trustees, officers, agents and employees as additional insured. Certificates of insurance are to be sent to the Director of Service Agreements, Columbia University, Purchasing Office, 615 West 131st Street, 3rd Floor, New York, NY 10027.

#### 12. Notices.

(a) All progress reports to be delivered to Columbia shall be addressed as follows:

(b) All other written notices to be delivered to Columbia shall be addressed to:

Columbia University 615 West 131<sup>st</sup> Street 3<sup>rd</sup> Floor New York, NY 10027 Attn: Joseph Harney

Vice President, Procurement

with a copy to:
Columbia University
Office of the General Counsel
412 Low Library
Mail Code 4308
535 West 116<sup>th</sup> Street
New York, NY 10027

(c) All written notices to be delivered to Service Provider shall be addressed to:

(d) Either party may change its addressee or other information by providing written notice thereof to the other party.

#### 13. Other.

- (a) Service Provider and its agents, contractors and employees entering upon Columbia's premises will take all proper and sufficient precautions and safeguards against the occurrence of any accidents, injuries (including death) or damages to any person or property.
- (b) Neither of us will attempt to assign this Agreement, in whole or in part, without the prior written consent of the other. Service Provider may not subcontract any of its obligations hereunder without Columbia's prior written consent. Any attempt to assign or subcontract without consent is void. Any approved subcontracts will be subject to all conditions of this Agreement, and Service Provider will be responsible for the performance of its subcontractors to the full extent as if employed directly by Service Provider.
  - (c) This Agreement does not create any right or cause of action for any third party.
- (d) Service Provider will perform the Services in accordance with all applicable laws, rules and regulations, including equal employment opportunity and import and export control laws and regulations. If Services are funded through a government grant or contract, Service Provider will comply with all laws, regulations, standards, and rules applicable to such grant or contract, as if they were fully set forth in this Agreement.
- (e) If any provision of this Agreement is held to be invalid or unenforceable, but would be valid and enforceable if appropriately modified, then such provision will apply with the modification necessary to make it valid and enforceable in accordance with its objectives. In any case, the remaining provisions of this Agreement will remain in full force and effect.
- (f) The failure or delay of either party to insist on strict performance of any term or condition, or to exercise any right or remedy in this Agreement, is not intended, and will not be construed as, a waiver of any such right or remedy.
- (g) Service Provider will maintain accurate and current accounting and financial records concerning its activities under this Agreement. Columbia or its designated representatives will have the right to audit (at Columbia's expense) Service Provider's books, records and operations to confirm compliance with its obligations under this Agreement.
- (h) Service Provider warrants that there exists no actual, potential or appearance of conflict between Service Provider's family, businesses, or financial interest and Service Provider's performance of the Services. Service Provider represents that it has not offered (and will not offer during the term of this Agreement) any compensation, reward, gift, favor, service, outside employment, reimbursement of expenses, loan, ownership interest, or anything else of monetary value, to any officer, employee, student, or faculty member of Columbia as an inducement to entering into or continuing under this Agreement. Service Provider will notify Columbia in writing of any change in conditions that might give the appearance of a conflict of interest. Service Provider will support and safeguard Columbia's legitimate interests in any dealings with third parties.
- (i) Service Provider is an independent contractor with respect to Columbia, and nothing in this Agreement constitutes the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking, or allow either party to create or assume any obligation on behalf of the other party for any purpose

whatsoever. Neither Service Provider nor its employees or agents will be entitled to any benefits applicable to Columbia's employees. Service Provider will be solely responsible for its compliance with all laws, regulations, and rules regarding employment of its personnel, and for any claims made by personnel or other individuals assigned by Service Provider to provide the Services, including any wages, benefits, workers' compensation, health and unemployment insurance, and pension contributions.

- (j) Service Provider acknowledges that Service Provider has received and reviewed a copy of the written Identity Theft Prevention Program (ITPP) maintained by Columbia University pursuant to the FTC Red Flags Rule, 16 C.F.R. §681.2
- (http://compliance.columbia.edu/docs/identify\_theft\_prevention\_policy.pdf). In performing activities in connection with a Covered Account (as defined in the ITPP), Service Provider and its personnel will maintain and observe policies and procedures to detect relevant Red Flags that may arise in the performance of the Service Provider's activities, and will take appropriate steps to prevent or mitigate identity theft. Service Provider agrees to report promptly and comprehensively to Columbia University in writing in the event Service Provider in connection with a Covered Account detects an incident of actual or attempted identity theft or is unable to resolve one or more Red Flags that Service Provider detects in connection with a Covered Account.
  - (k) Service Provider acknowledges below listed commitments, but are not limited to the following:
  - (i) Anti-Bribery: Service Provider will take no action, or omit to take any action, that would violate or cause Columbia to be in violation of, applicable anti-bribery and other anti-corruption laws, including, without limitation, the U.S. Foreign Corrupt Practices Act. Service Provider agrees that in connection with this Agreement, Service Provider will not offer, pay, promise to pay, or authorize the payment of, directly or indirectly, money or anything of value to any entity or other person of any type (including, but not limited to, any government official, official of any public international organization, political party official, or political candidate) for the purpose of influencing any act or decision or to secure any other improper benefit or advantage.
  - (ii) Other Laws: Service Provider will take no action, or omit to take any action, that would violate or cause Columbia to be in violation of, applicable laws, including, but not limited to, U.S. trade controls, export, and anti-boycott laws and regulations. Service Provider represents and warrants that it and all other resources engaged directly or indirectly by Service Provider in connection with this Agreement are not themselves (nor are they owned or controlled, in whole or in part, by others that are): (a) debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any governmental department or agency, (b) subject to U.S. trade sanctions or restrictions, (c) on the U.S. Treasury Department's Specially Designated Nationals list (<a href="www.treasury.gov/sdn">www.treasury.gov/sdn</a>), or (d) otherwise restricted, embargoed, or prohibited under applicable law from entering into agreements with U.S. entities and individuals.
  - (iii) <u>Political Activity:</u> In connection with this Agreement, Service Provider will not attempt to influence the outcome of any election for public office, carry on any voter registration drive, support lobbying activity, or otherwise support attempts to influence local, state, federal, or foreign legislation.
  - (iv) <u>Continuing Representations:</u> Without limitation of Service Provider's other obligations, any failure to comply with the provisions of this section will be deemed a material breach of contract. Upon Columbia's request, Service Provider will provide documentation and records demonstrating its compliance with this section.
- (I) This Agreement is the complete agreement between Columbia and Service Provider regarding its subject matter, and replaces any prior oral or written communications between them. Any modification to this Agreement must be made in writing and signed by authorized representatives of both parties. Any variance from or addition to the terms and conditions of this Agreement in any present or future invoice or other document delivered by Service Provider will be void and of no effect unless agreed to in writing by

an authorized representative of Coll	olumbia.
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(m) In case of a conflict between the provisions set forth above and the Statement of Work or other attachment to this Agreement, the provisions set forth above will govern, unless otherwise specifically agreed in writing.This Agreement may be signed in two or more counterparts, each of which shall be an original, but all of which shall constitute one and the same instrument.

Each of the parties has caused this Agreement to be executed on its behalf by its duly authorized representative.

 Signed:
 Signed:

 "Service Provider"
 The Trustees of Columbia University in the City of New York

 Sign:\_\_\_\_\_\_
 Sign:\_\_\_\_\_\_

 Name:\_\_\_\_\_\_
 Name:\_\_\_\_\_\_

 Title:\_\_\_\_\_\_
 Title:\_\_\_\_\_\_

 Date:\_\_\_\_\_\_\_
 Date:\_\_\_\_\_\_\_

## APPENDIX B

## Test Protocols & Schedule

Study-specific test
HIV Antigen and Antibodies, Fourth Generation w/Reflexes
Anti-HBs
Anti-HBc
HBsAG
Hepatitis A virus test (HAV)
Hepatitis C Viral RNA, Quantitative
Hepatitis C Viral RNA, Genotype
Electrolyte Panel
Urinalysis Complete
Serum Creatinine
Chlamydia/N. Gonorrhoeae RNA, TMA, Urogenital
Chlamydia trachomatis/Neisseria gonorrhoeae Rectal
Chlamydia trachomatis/Neisseria gonorrhoeae Throat
Syphilis test/RPR (diagnosis)
CBC (includes Differential and Platelets)
Phosphorous
Prothrombin Time with INR
Aspartate aminotransferase
Alanine aminotransferase
Alkaline phosphatase
Total bilirubin
Albumin