REQUEST FOR PROPOSAL

Title: BREEDING AND MANAGEMENT OF MINIATURE SWINE COLONY on behalf of Columbia’s Center for Translational Immunology (CCTI)

RFP Issue Date: July 15, 2019

RFP Due Date/Time: 5 PM, August 8, 2019

Location:
Columbia University
Procurement Services
615 West 131st Street, 3rd Floor
New York, New York 10027

Columbia RFP Representative(s):

Name: Michael Reich
Title: Director for Lab & Medical Sourcing
Phone: 212.854.2337
E-mail: mmr62@columbia.edu

Name: Jennifer Colozzi
Title: Chief of Staff / CCTI
Phone: 212 305 0198
E-mail: jcc2200@cumc.columbia.edu
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information &amp; Instructions for Bidders</td>
<td></td>
</tr>
<tr>
<td>Section 1 General Information for Bidders</td>
<td>3</td>
</tr>
<tr>
<td>Section 2 Submission of Bids</td>
<td>6</td>
</tr>
<tr>
<td>Section 3 Evaluation of Bids</td>
<td>9</td>
</tr>
<tr>
<td>Section 4 University/ Project Background Information</td>
<td>12</td>
</tr>
<tr>
<td>Bidder’s Declaration Section 5</td>
<td>15</td>
</tr>
<tr>
<td>Bidder Questionnaire Section 6</td>
<td>16</td>
</tr>
<tr>
<td>Scope of Work (SOW) Section 7</td>
<td>20</td>
</tr>
<tr>
<td>No Bid Form</td>
<td>26</td>
</tr>
<tr>
<td>Contract Acknowledgement</td>
<td>27</td>
</tr>
<tr>
<td>Appendices</td>
<td></td>
</tr>
<tr>
<td>Appendix A Columbia’s Services Agreement</td>
<td>28</td>
</tr>
<tr>
<td>Appendix B Suggested Proposal Budget Form for Cost Evaluation - Attachment</td>
<td></td>
</tr>
</tbody>
</table>
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: BREEDING AND MANAGEMENT OF MINIATURE SWINE COLONY

Bid Deadline: 5 PM, August 8th, 2019

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: Jennifer Colozzi
Title: Chief of Staff / CCTI
Phone: 212 305 0198
E-mail: jcc2200@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, religion, 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 July 19, 2019. All questions regarding the RFP shall be directed to the 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 July 26, 2019.

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 July 30, 2019.**

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

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

Bid Modifications: 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.

Bid Withdrawal Notifications: 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, reliability and reputation.
- The overall long term cost to Columbia.
- Regulatory compliance/certifications.

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 which is substantially the same as the contract included with this RFP. In no event is a Bidder to submit its own standard contract terms and conditions as a response to this RFP. 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**

- **July 15th**: Request for Proposals Posting
- **July 18th**: Pre bid Tele - Conference Call 12:00 Noon – 2:00 PM EDT
July 19th  Deadline for Questions & Requests for Clarifications
July 26th  Deadline for Responses by Columbia
August 8th  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 CCTI 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.

**Deadline**

Proposals should be submitted by August 8, 2019. 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. Those who provide terms opposing the RFP terms will be considered non-responsive. All proposals should be submitted as a single pdf document containing components listed.

Questions must be addressed to: Jennifer Colozzi jcc2200@columbia.edu and Michael Reich mmr62@columbia.edu
General Information

Institute Background Information:

The Columbia Center for Translational Immunology (CCTI) at Columbia University Medical Center (CUMC) is a multi-departmental, multidisciplinary research center aimed at optimizing translation of advances in basic immunology from the laboratory to the clinic, understanding immunological diseases and events in humans and optimizing transfer of information and methodologies to achieve synergy between different disciplines of applied immunology.

Columbia has the largest organ transplant program in the country, and a major reason for establishing the CCTI was the need for an in-depth laboratory research program focused around the extraordinary potential provided by this clinical transplant program. The Center was established in April 2010 and currently includes 20 faculty members, including 17 Principal Investigators. The CCTI includes laboratories working in various areas of organ transplantation, hematopoietic cell transplantation, Type I diabetes, other areas of autoimmunity, tumor immunology, stem cell biology and basic immunology.

Project Background Information & Objectives:

In order to support the above research the CCTI maintains a miniature swine colony. The lines in this herd have been developed over the past 40 years by Dr. David H. Sachs using selective breeding to establish miniature swine with defined MHC genes as a large animal model for studies of transplantation biology. In pigs, the MHC is referred to as the swine leukocyte antigen (SLA) system. We currently maintain a variety of lines that are homozygous for three different MHC haplotypes (SLAa, SLAc and SLAd) and six lines bearing different intra-MHC recombinant within those haplotypes. One subline of the SLAdd line has been maintained over the last 15 years by sequential brother-sister mating, to produce a fully inbred line of miniature swine that now has a coefficient of inbreeding of >97%. Starting in 2000, additional lines with the 1,3-galactosyltransferase gene knocked out were derived and continue to be manipulated with the addition of new genes that are the cornerstone of xenotransplantation research being conducted at CCTI and elsewhere.

The herd is managed as a closed herd, isolated from all other animals. The colony census is currently at ~300, consisting of fourteen different lines of inbred and genetically modified lines. The current demographics of the herd are in the table below. This herd provides animals for allografting of Kidney, Lung and Composite Tissue Allografts as well as founders for Caesarian-derived Porcine Cytomegalovirus free (pCMV-free) genetically modified miniature swine for Xeno Kidney and Lung transplantation. For this purpose, we currently breed sufficient animals from each line to perpetuate that line and provide for research needs, which translate to approximately a total of 10-12 pregnancies per month. All animals produced are genotyped, identified, vaccinated, reared, dispensed and/or expanded for supporting all ongoing internal and external research needs. The herd management should be requiring at minimum one full-time Facility Manager/Herdsman and 5 part-time (32 hours/week) Animal Technicians.

The Columbia Center for Translational Immunology is requesting proposals for the management of this miniature swine colony. Activities will include FDA, Veterinary and IACUC oversight of the breeding production of certain lines of genetically modified pigs for research purposes.
Contract Type

CCTI seeks to award a contract for the breeding and management of its MHC inbred miniature swine colony in one of two proposed contract scenarios.

1. Breeding and management of the swine colony at Bidder’s facility – Fully outsourced contract.
2. Breeding and management of the swine colony at a leased facility at upstate NY – Partial service contract.

CCTI has no stated preference as to the type of contract desired. The ultimate goal being the smooth breeding and management of the colony in a cost effective operation that is transparent, regulatory compliant and responsive to the research needs of CCTI.

Fully outsourced contract bids are expected to meet the following requirements:

1. The facility must be adequate for housing the colony with the demographics outlined below, and must also meet the space, flooring, caging, ambient environmental and ventilation design requirements recommended for the pigs by the ILAR guide. Provider(s) capable of offering a contiguous facility and additional space if and when necessary are preferred.

2. The building housing the pig herd must be completely isolated from any other animals. Providers with exclusive space for housing the pig herd are preferred. Any other pigs if housed on the premises must be procured from USDA/AALAC/FDA approved or regulated commercial breeders and/or research organizations, AND must meet the health status requirement of the pig herd. In addition the staff working with pig herd may not have direct/indirect exposure/contact with the other pigs onsite or offsite.

3. The equipment, supplies, feed and other inanimate items used for managing the pig herd must be held for the exclusive use of the CCTI herd.

<table>
<thead>
<tr>
<th>Areas needed</th>
<th>Anticipated # Animals</th>
<th>Minimum Floor Space (Sq. ft)</th>
<th>Facility /Room Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sow Breeding</td>
<td>100</td>
<td>2500</td>
<td>Breeding sows should be physically isolated from other animals. The room(s) should have separate air in, modular penning to allow size adjustments for maximizing efficiency for size or group housing. Contiguous to farrowing room(s)</td>
</tr>
</tbody>
</table>
Breeding Boars should be physically isolated from other animals. The room(s) should have separate air in, modular penning to allow size adjustments for maximizing efficiency for size. Contiguous to farrowing room(s).

Contiguous to farrowing room

Ideally split between 2 rooms and contiguous to sow breeding and nursery

Dedicated HVAC system providing 100% HEPA filtered air (no less than MIRV 14) and maintained at positive air differential to rest of facility

Room should have negative air flow. Airlock entrance is preferred.

All rooms must be isolated from other pigs, ideally all other animals. The rooms should be equipped with controls for regulating temperature and humidity inside the rooms, and should also have some form of air filtration.

Partial Service Contract bids must include the services of facility general maintenance (Cleaning, sanitation of floors and bathrooms etc) for the contracted vivarium facility, procurement of supplies needed to facilitate the management of the colony, management for sub contractors or vendors providing goods and/or services (e.g. telecom, internet) necessary for the functional operation of the facility for CCTI.

Bidders interested in offering the Partial Service Contract bid must contact CCTI for the details about the potential contract facility.

Please see Section 7 Scope of Work for further requirements details.

Eligibility Requirements:
Prospective Bidders must be capable of offering their own Veterinary and IACUC oversight, as well as USDA certification. OLAW, AAALAC and AACLAM certification(s) preferred.
Section 5
Bidder’s Declaration

This Bid is in response to Columbia’s request for a Bid ("RFP") for Breeding and Management of Miniature Swine Colony.

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 Address

________________________________________
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 location of each of your firm's offices. Indicate which office would service this account.

3. Please list your firm's 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?

4. 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.

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.

6. Please indicate if your business operates in the following locations:
   
   Zip Codes –
   
   - 10025 – 10027
   - 10029 – 10040
   - 10451
   - 10454 – 10455
   - 10474

   New York Boroughs –
   
   Brooklyn ___ Queens ___ Bronx ___ Staten Island ___ Manhattan ___

7. As Columbia is committed to the hiring of qualified local residents from the above mentioned local areas when possible:
   - Does your proposal address the hiring of local residents?
   Has your company engaged local talent in any previous engagements (through any contract whether or not with Columbia)? If so, please describe.

**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, 2nd 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?
Section 7
Scope of Work (SOW)

The Columbia Center for Translational Immunology (CCTI) intends for selected PROVIDER to provide: A suitable animal vivarium facility in the New York area and/OR management services for its miniature swine production colony. Activities will include USDA, FDA, Veterinary and IACUC compliant oversight of the production of fourteen lines of normal and genetically modified miniature swine for research purposes. This herd provides animals for allo-transplantation of Kidney, Lung and Composite Tissue Allografts as well as founders for Caesarian-derived Porcine Cytomegalovirus free (pCMV-free) genetically modified miniature swine for Xeno Kidney and lung transplantation. For this purpose, PROVIDER will breed sufficient animals from each line to perpetuate that line and provide for research needs as communicated by the CCTI project officer (PO). It is anticipated that this task will translate to approximately 10-12 pregnancies per month, resulting in approximately 3-4 viable offspring/litter. All animals produced will be genotyped and identified (RFID chip, Tattoo, ear tag, as determined in consultation with PO) at or before weaning to assure that appropriate animals are provided for all supported research. Ongoing improvements to protocols for hand-rearing highly inbred and genetically modified miniature swine will be made in consultation with the PO, in order to reduce pre-weaning mortalities and increase the availability of these very high value animals for research.

The PROVIDER assumes the responsibility and accountability for the following activities/services for the colony:

- **Development of Standard Operational Procedures and Best Practices**
  - Develop standard operational procedures (SOP) and best practices to ensure regulatory compliance (USDA, OLAW, & AAALAC) and achieving consistency in the operational efficiency and production performance of the herd.
  - The SOPs and best practices must be developed in consultation with the CCTI Project Officer (PO), and CCTI veterinarian for all the services performed.
  - The PROVIDER must consult with PO prior to modifying any SOPs or best practices previously approved by CCTI. The PROVIDER must also document and report any deviations from the SOPs and best practices to CCTI.
  - The SOPs and best practices will be designed to promote consistent reproductive performance of the herd and any other key performance indicators established by the PO and regulatory authorities.

- **Development and Measurement of Key Performance Indicators**
  - The key performance indicators for measuring the overall performance of the colony will be developed, measured, monitored, and controlled for each breeding line in collaboration with PO, with written documentation of these indicators, including but not limited to number of piglets born live, pre-weaning mortality, farrow percentages, weaning weights etc.,
  - The PROVIDER must maintain close communication with CCTI through the PO, and proactively seek guidance for preventing or mitigating potential animal health, welfare and reproductive performance issues while performing the services below and other services to be determined by CCTI PO.

- **Regulatory Requirements**
  - The Provider must keep CCTI PO and Columbia Veterinarians up to date on the regulatory matters, including pending inspections and compliance issues if any.
The PROVIDER facility should be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and OLAW assured (or provide required steps and time line to acquiring both). The PROVIDER must have an established, functioning IACUC, USDA license, and licensed veterinarian(s) with appropriate state-controlled substance and DEA licenses.

- A licensed regulated waste disposal company must be used for all animal carcass disposal, and disposal documentation must be maintained as per the FDA requirements for all animals.
- All documentation relevant to the breeding and maintenance of the colony must be available to CCTI PO.

### Animal Care and welfare

- Animals to be fed with prescribed diets and feed levels as documented in the SOP. The animals must be fed daily, including weekends and holidays. Any change to the diet or schedule must be communicated to the CCTI PO for guidance and approval.
- Ensure strict environmental (Temperature, Humidity, Air changes etc..) controls. Environmental controls must be maintained and documented to satisfy all regulatory requirements.
- Provide animals with environmental enrichment as directed by the CCTI PO. Daily cleaning of facility following the standard operational protocol for sanitation and disinfection of the floors, cages, feeders, waterers and rooms.

### Biosecurity and Animal Health

- Maintain a closed herd as directed by the PO, CCTI veterinarian and herd manager.
- Maintain strict biosecurity measures to prevent exposure to swine pathogens or to any other swine not part of the CCTI research program.
- Staff must avoid direct or indirect contact with pigs outside the work place. In the event of an accidental contact with pigs outside the work place, a mandatory cleanup process according to an approved SOP must be accomplished before entering the facility. This includes a minimum downtime of 24 hours, taking a shower and changing into clean clothes before entering the facility.
- Develop a vaccination schedule for the herd in consultation with the CCTI PO, veterinarian and herd manager; and then perform the vaccinations according to a schedule developed in consultation with the PO.
- Complete bi-annual herd health screening at a facility of CCTI’s preference
- Complete daily health checkups on all animals. Record the observations and treat animals as needed. All health observations and treatments to be recorded in CUMC web accessible application provided by PO.
- Only AVMA-approved euthanasia methods for swine to be used. PROVIDER should make best effort to consult CCTI PO on euthanasia of animals based on veterinary discretion.

### Animal Breeding

- Perform daily estrus detection by making use of a teaser boar, in females assigned to breeding, and document the findings.
- Perform semen collection, analysis, dilution and incubation of sperm for artificial insemination of the sows in estrus.
- Perform breeding services including but not limited to artificial insemination, hand mating and harem breeding following breeding advice from CCTI PO and herd manager.
- Perform pregnancy detection using ultrasound at least 25-30 days post-breeding or as requested by PO.
- Move pregnant sows (approximately 10-12/ month) to farrowing crates at least five
days before the due date.

✓ Provide farrowing assistance to farrow high-value litters as determined by CCTI PO, approximately 1-2 litters/month.
✓ Ensure proper colostrum intake in all newborn piglets within 6-12 hours after birth.
✓ Foster piglets in case of inadequate milk production or poor mothering abilities.
✓ Hand rear high value and other piglets as requested by PO, in suitable environment including nurtinger, birthingdecks, incubators etc., approved by PO.
✓ Wean sows at 4-5 weeks or as directed by the PO or CCTI veterinarian.
✓ Provide heat stimulation to weaned sows making use of flush feeding, light stimulation, boar stimulation and hormone treatments as directed by PO.

- **Rearing of Replacement Animals**
  ✓ Follow the prescribed programs (SOP and Best Practices) for replacement of gilts and boars.
  ✓ Replacement gilts assigned to breeding to be exposed to boar stimulation and checked for estrus as directed.
  ✓ Replacement boars assigned for breeding to be trained for semen collection using a dummy sow.
  ✓ The provider must keep CCTI PO up to date on any health, conformation or other concerns.

- **Identification and Record Keeping**
  ✓ Animals must be identified within the first 24 hours after birth with a unique ID supplied by CCTI. Animals will be identified with ear tags, tattoo and/or RFID chips as directed by PO.
  ✓ Staff and other key personnel are expected to record all herd related data in CUMC web accessible application including animal location, movements/shipping, health observations, vaccinations and treatments, tissue and blood harvests, breeding and production information, and other relevant info as requested by CCTI PO.
  ✓ Appropriate methods for validating animal identification prior to any procedure, including breeding, bleeding, animal shipment and euthanasia should be developed and updated as necessary.

- **Sample Collection and Animal Shipments**
  ✓ Perform the blood and tissue collections and shipments to CUMC and collaborators, as directed by CCTI PO, including:
    o weekly typing bleeds (~5ml each) from 5-10 animals typically >4 weeks of age
    o weekly bleeds 50-200 ml from 3-5 designated adult bleeders
  ✓ Collect and prepare tissue samples as directed by CCTI PO and ship to CUMC and collaborators.
  ✓ Prepare animals for shipment, perform exit examination including required USDA and FDA paperwork and load animals on transport vehicles as directed by CCTI PO.

**pCMV-free derivation**

Genetically modified founders identified for Xeno Kidney and Lung Transplantation will undergo non-survival caesarian section. The newborn piglets will be handled aseptically and moved across the pCMV barrier into a pCMV-free room dedicated for hand rearing. This room must be equipped with a dedicated HVAC system providing 100% HEPA filtered fresh air and maintained at a positive air pressure differential to the rest of the facility. All staff entering this room must shower and change into clean Tyvek suits, gloves and protective footwear before entering the area. Piglets will be hand reared up to a weaning age of 5 weeks. After weaning pigs will be maintained and grown within the pCMV barrier to ensure maintenance of pCMV-free status. pCMV-free pigs from outside contractors will be
shipped to the facility at an age of 4-6 weeks for holding and maintenance of the pCMV negative status. Upon request from CCTI PO, pigs will be shipped to Columbia University or third parties authorized by CCTI/ Columbia University. In order to prevent exposure to pCMV pigs will be transported using HEPA filtered shipping cages. Pigs will be subjected to serological or nucleic acid based pCMV testing at a facility of CCTI’s preference or moved back to the breeding colony or the spleen harvested for pCMV testing. Pigs may be retested for pCMV upon request by PO before shipment.

The scope of work identified activities and process shall substantially apply whether final awarded contract shall be a fully outsourced contract at bidder’s facility or partial service contract at leased vivarium.

Successful bidder shall submit financial proposal that will allow CCTI to budget outsourced services in a consistent, auditable and transparent manner.

Successful contractors shall manage to the following operational objectives. Proposals are expected to include bidders suggestions how to maintain operational levels ongoing basis:

1. No Biosecurity Breach during operations – Create biosecurity checklist including restricted facility access, vermin detection in place and containment, dedicated covering for personnel and washing stations.

2. On going communication and collaboration with PO to identify and resolve issues to the satisfaction of CCTI. This should include guaranteed responsiveness and prompt issue resolution requiring operational changes and reasonable turnaround on facilities issues (1 week).

3. Timely completion of tasks and corrective actions for identified issues agreed upon by contractor and PO. Tasks should have clearly identified ownership responsibility.

4. Demonstrated transparent proactive communications to foster a collaborative working relationship. Weekly scheduled meetings with updates on herd census, pigs born etc.

5. Consistent and predictable budgeting allowing for cost containment with no surprises.

The attached Proposal Budget Form for Cost Evaluation is a suggested draft that offers a suggested costing model. Bidders may suggest a different format as long as costs are easily identifiable, auditable and transparent.
The proposals requested must be detailed and show all variable affecting cost and service levels.

**Successful proposals must provide at minimum following information:**

1) **Readiness to start** (i.e. timeline to be ready to receive first swine)
2) **A complete facility description including floor plans, environmental controls, penning layouts and operational SOPS, as applicable for Full service Bids.**
3) **Summary of qualifications to operate a biosecure facility and the required biosecure C-section surgeries.**
4) **Summary of experience in working collaboratively with an academic institution to comply with all government and animal regulatory agencies.**
5) **Summary of procedures and protocols in place for ensuring biosecurity.**
6) **Team qualifications** (one page vitae for each Key Person outlining expertise in veterinary oversight or care, facility management and C-section experience). Staffing details including proposals to increase, decrease or replace current staff, benefits etc. for the work proposed
7) **Additional resources available including**
   - Staff and experts which can be leveraged during heavy swine census periods
   - Swine pathogen control and troubleshooting staff and experts
8) **COMPLETED and detailed BUDGET FORM FOR PROPOSED COSTS (sample attached)**
9) **Current certifications and liability insurances (or proof of insurability)**

In addition to the above, **Full Service** providers must also include the following

10) **Physical Address and floor plan of the existing/planned facility, indicating biocontainment features, and surgery, animal housing and storage areas.**
11) **IF SET UP COSTS ARE NECESSARY FOR FULL SERVICE**
   - Facility maintenance/renovation costs for set up (these costs need to be well-justified and these will ONLY be reimbursed after expenditure and verified installation/completion); no overhead costs/management costs will be allowed on this aspect of the proposal if approved. Preference will be given to proposals that do not require set up capital budget advance requirement.
12) **Current certifications and liability insurances (or proof of insurability)**
13) **Include a video tour of actual space to be occupied**
14) **Provide any relevant background information supporting facility’s qualifications to support the project on a sustainable long term basis.**

**Executive Summary:** Describe how your proposal meets the requirements outlined above. Proposals must include detailed purchase, costs, shipping and housing costs by weight, crate charges and overhead. Funding for this research is sponsored and vendor must be able to comply with federal cost reporting requirements.

**Fees:** Provide a preliminary fee structure that includes pricing options.

**Timeline:** Submit a proposed timeline that includes phases of implementation and requirements to meet that schedule.
NO-BID FORM

RFP TITLE: __________________________

RFP #: __________________________

Bidders choosing not to bid are requested to complete the portion of the form below:

It is our intention not 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)

________________________________________________________
________________________________________________________
________________________________________________________

Signature: __________________________
Name: __________________________
Title: __________________________
CONTRACT ACKNOWLEDGMENT

DATE:  July 15, 2019

FROM:  Vendor Name

Address

TO: Columbia University in the City of New York

RE: PROPOSAL/BID DESCRIPTION

Project Description

Quotation #

Please be advised that we have carefully read the Appendix “A”, (agreement type) enclosed in the package. We acknowledge that if we are ultimately awarded the contract we will promptly execute an agreement containing substantially similar terms and conditions.

(Please note any contract exceptions in the space below or provide an attachment with appropriate signature. Type NONE if you do not have any exceptions.)

Note Exceptions:

__________________________________________

__________________________________________

__________________________________________

__________________________________________

__________________________________________

Signature: _________________________________

Name: _________________________________

Title: _________________________________
APPENDIX A

Agreement for Breeding and Management
of Miniature Swine Colony

Service Provider Agreement (“Agreement”) dated as of XXXX, 2019 (the “Effective Date”) between The Trustees of Columbia University in the City of New York (“Columbia”), for the Columbia Center for Translational Immunology (“CCTI”), and XXXXX (“Service Provider” or “XXXXX”). Columbia and XXXXX are collectively referred to herein as the “Parties.”

1. Scope. Service Provider agrees to perform the services described in this Agreement (the “Services”). In general, the Services consist of management and production of 14 lines of normal and genetically modified miniature swine (the “Sachs Swine”) for research purposes, all as more specifically described in the Statement of Work attached hereto as Exhibit 1 and incorporated in this Agreement by reference (the “Statement of Work”).

2. Payments. Conditioned upon Service Provider’s performance of the Services in accordance with this Agreement, Columbia will pay Service Provider for all amounts invoiced as per rates and costs specified in the proposal from XXXX dated XXXX, 2019 attached hereto as Exhibit 2 (the “Proposal”). The rates and costs specified in Exhibit 2 represent Columbia’s financial commitment to Service Provider for Services and deliverables, and other obligations under this Agreement. In the event Service Provider will provide additional work not specified in the Services, such work and costs must be approved by Columbia in writing before the work is performed by Service Provider.

All invoices will be forwarded to Jennifer Colozzi, Chief of Staff, via email at jcc2200@cumc.columbia.edu, with a copy to Seth Mayersohn, Director of Business in Columbia’s Institute of Comparative Medicine (“ICM”) at sm3580@cumc.columbia.edu. Billing shall be on a monthly basis, net 45 days. Each invoice shall be in accordance with the costs and prices for services set forth in the Proposal, and shall be sufficiently detailed to enable CCTI to confirm the calculation of charges for services performed.


(a) Service Provider will perform the Services in a timely and professional manner and in accordance with (i) the requirements set forth in the Statement of Work and the Proposal, as well as this Agreement; (ii) the standards set by the U.S. Department of Agriculture (“USDA”) and AAALAC International (“AAALAC”); and (iii) all other applicable standards of any federal, state or local government or government agency. Service Provider further agrees that all Services shall be performed by qualified personnel in accordance with its own policies and standard operating procedures (“SOPs”), which shall be in compliance with all applicable federal, state and local laws and regulations. Service Provider will provide copies of all of its SOPs applicable to the care of the Sachs Swine to Columbia and will consult with Columbia Columbia’s ICM and CCTI on any aspect of its SOPs identified by Columbia as concerns.

(b) Service Provider will assign qualified and experienced personnel to perform the Services. Where the Proposal 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 the Proposal, 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) At least annually, the Parties will jointly review the standard operating procedures, performance of the animal colony, welfare of the animals, and the level of staffing required to provide the Services and whether any
changes to the operational processes, standard operating procedures, and increase (or decrease) in personnel is appropriate. Any proposed increase (or decrease) in personnel and related increase (or decrease) in costs will be subject to Columbia’s written consent.

(d) If Columbia informs Service Provider of a deficiency in the deliverables or Services, Service Provider will promptly make corrections and inform Columbia of corrections made. Service Provider will not charge Columbia for the time and expense in making corrections to service levels or maintenance 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 this Agreement, 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 other requirement articulated and set forth in the Statement of Work and the Proposal.

(e) Service Provider will provide timely and complete status and other reasonable reports as required by Columbia. Status reports will identify anticipated or actual deviations from SOPs, service levels or quality of care 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 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.

(f) Service Provider will maintain appropriate records of events associated with the Animal Husbandry (identification, farrowing dates, feeding, housing, health and treatments, mortalities, vaccination records etc.,) welfare, management and transport of the animals of the Sachs Swine, including through use of the Animal Tracking System (“ATS”) database or a Columbia-designated replacement database. Animal Identification numbers for the newborn piglets will be provided by CCTI. Piglets will be identified with an ear tag and tattoo within the first week after birth. Piglets will also be micro chipped upon CCTI’s request.

(g) Representatives of CCTI, Columbia’s ICM and Columbia’s Institutional Animal Care and Use Committee (“IACUC”) may plan and schedule visits regarding the care and use of animals at the housing facility at their discretion. Service Provider shall provide the semiannual inspection reports and semiannual program reviews of Service Provider’s IACUC to the Columbia IACUC and ICM. Service Provider will notify Columbia’s Attending Veterinarian and IACUC of any changes in Service Provider’s USDA registration or other regulatory status, or its AAALAC accreditation (once obtained) within 24 hours. Service Provider will promptly notify Columbia/CCTI, in advance if feasible, of any inspection by governmental authorities relating to the Sachs Swine, and will provide Columbia/CCTI with copies of the results of such inspection and any correspondence with or reports to governmental authorities concerning the Sachs Swine. Service Provider will notify the Columbia Attending Veterinarian of any veterinary emergencies concerning the Sachs Swine and of any issues related to reportable regulatory non-compliance within 24 hours.

(h) In the event that Service Provider is not currently accredited by AAALAC, Service Provider will make best efforts to obtain full accreditation by AAALAC within three (3) years and six (6) months of the Effective Date. Service Provider will commence such best efforts no later than six (6) months after the Effective Date, and will regularly inform Columbia of its progress toward accreditation.

4. Ownership and Use of Animals; Transport.

(a) Service Provider shall assume ownership of each animal covered under this Agreement at the time such animal is loaded for transport to the housing facility or, in the case of piglets delivered at the facility] at the time of such delivery. The Sachs Swine will be housed and maintained solely for use in research or in further breeding for research purposes, as designated by Columbia, and shall not be bred or studied by Service Provider for Service Provider’s own purposes or the purposes of any third party.

(b) Upon written authorization from Columbia’s ICM, Service Provider will transport the Sachs Swine to and/or
from Columbia and from the facilities of third parties. The Sachs Swine and any cells, tissues or derivatives therefrom will not be sold, loaned, donated or otherwise transferred to any person, facility or entity other than Columbia, or used for any purpose other than as set forth herein, without Columbia’s prior written consent.

(c) The Parties understand that genetically modified animals, including certain lines of the Sachs Swine that are genetically modified (the Sachs GM Swine”) and associated derivatives (organs, tissues, cells) or progeny therefrom are regulated by the Food and Drug Administration Center for Veterinary Medicine (FDA CVM) and that the Sachs GM Swine are subject to a Veterinary Master File (VMF) that requires documenting the transfer of the Sachs GM Swine or derivatives therefrom. The Parties agree to work together to properly document and communicate to FDA CVM any shipment or transfer of animals as required and to comply with all other regulatory requirements with respect to the VMF and, in connection therewith, Service Provider will notify Jennifer Colozzi, Amarnath Dasari or Dilrukshi Ekanayake-Alper of CCTI, or such other representative of CCTI as Columbia may hereafter designate in writing, in advance of the date of any proposed shipment or transfer of animals in order to facilitate such documentation and communication with FDA. Service Provider will maintain all records relating to the Sachs GM Swine and any transfers thereof required by FDA and will preserve such records for at least the period required by FDA. All such records shall be Columbia Confidential Information as described in Article 6, below, and shall be subject to the obligations of confidentiality set forth therein.

5. 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 regulations and laws; and (iii) through experienced individuals certified and 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 the Statement of Work and the Proposal. 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 provide the Services for Columbia in accordance with this Agreement.

6. Confidentiality.

(a) Service Provider will treat as confidential all data, records, accounts, and other information regarding CCTI, Columbia and its affiliates that become known to Service Provider or are generated by Service Provider through its activities hereunder or any previous activities involving the provision of services relating to the Sachs Swine, including, but not limited to, all information regarding the Sachs Swine, information regarding CCTI or Columbia’s and its affiliates’ operations, research, policies, procedures, faculty, employees, students, information technology systems, and financial information and plans (“Columbia Confidential Information”). Columbia Confidential Information includes the Services and maintenance provided under this Agreement. Service Provider’s confidentiality obligations include establishing and maintaining appropriate safeguards, procedures, and systems to avoid the unauthorized destruction, loss, alteration, access to, or disclosure of any Columbia Confidential Information and animals under its care, in accordance with the standards of the applicable industry and as otherwise required by applicable law.

(b) Columbia will treat as confidential all of Service Provider’s proprietary methodologies, software and materials that Service Provider provides to Columbia hereunder and which are marked “Confidential” or “Proprietary”
In no event will Service Provider Confidential Information be deemed to include any Columbia Confidential Information.

(c) During and after the term of this Agreement, neither party will use or disclose the other party's Confidential Information, except for the purpose of providing, receiving or using the Services in accordance with this Agreement, or as may be required by law, regulation or court order. Service Provider will obtain from all subcontractors and agents authorized to perform the Services under this Agreement a signed written statement agreeing to the confidentiality provisions herein.

(d) The obligations of confidentiality under this Section do not apply to any information to the extent it: (i) was known to the receiving party prior to such party's receipt of or access to that information under this Agreement or in connection with any previous activities involving the provision of services relating to the Sachs Swine, (ii) was or becomes a matter of public information or publicly available through no act or failure to act on the part of the receiving party, (iii) is acquired from a third party entitled to disclose the information without obligation of confidentiality, or (iv) is developed independently and without use of the disclosing party's Confidential Information.

(e) Service Provider shall immediately notify Columbia/CCTI in the event of any loss or unauthorized disclosure of any Columbia Confidential Information, or of a request for disclosure of any such information by any third party.


(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. Service Provider will not assert any claim of ownership with respect to any intellectual property in the Sachs GM Swine, or any cells, tissues or derivatives therefrom.

(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) 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 the City and County of New York.

9. **Use of Name.** Service Provider will not use the name, insignia, or symbols of CCTI or Columbia, its faculties or departments, or any variations or combination thereof, or the name of any trustee, faculty member, other employee, or student of Columbia for any purpose whatsoever without Columbia’s prior written consent.

10. **Term and Termination.**

    (a) The term of this Agreement is from the Effective Date to XXXX, 20XX, unless otherwise terminated in accordance with this Section; provided, however, that the Agreement may be extended for an additional term or terms of one (1) year each in a writing signed by a duly authorized representative of each Party.

    (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.

    (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 Sachs Swine under its care and all cells, tissues and derivatives therefrom and/or ship said animals and/or materials to another service provider or location as designated by Columbia. Service Provider will return all 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 $2,000,000 per occurrence and $5,000,000 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) Professional Liability insurance, the Service Provider shall maintain limits not less than $1,000,000 per occurrence and $1,000,000 annual aggregate covering the errors and omissions of the Service Provider.

4) Each of the policies required by subsections (1) and (2.ii) above shall provide that the insurance company will 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, with the exception of Professional Liability, 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. The Service Provider shall provide Columbia University with 30 days prior written notification if their Insurance is cancelled or a material change has been made to their policy. Each certificate of Insurance will list the certificate holder as The Trustees of Columbia University in the City of New York, ATTN: Risk Management, 615 West 131st Street, 3rd Floor, New York, NY 10027.

12. **Notices.**

(a) All service and maintenance reports to be delivered to Columbia shall be addressed as follows:

   Columbia Center for Translational Immunology
   Columbia University Medical Center
with a copy to:

Institute of Comparative Medicine
Columbia University
650 West 168th Street
Black Building 18th Floor, MC1810-D
New York, NY 10032
Attn: Brian Karolewski, VMD

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

Columbia University
615 West 131st Street
3rd Floor
New York, NY 10027
Attn: Hugh Horowitz
Executive Director, Purchasing

with a copy to:

Columbia University
Office of the General Counsel
412 Low Library
Mail Code 4308
535 West 116th Street
New York, NY 10027

and:

CCTI Department of Medicine
Chief Of Staff
650 West 168th Street
Suite 1501
New York, NY 10032

(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 will take all proper and sufficient precautions and safeguards against the occurrence of any accidents, injuries (including death) or damages to any person or
(b) Neither party 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 allows 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) 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 Columbia.
(k) In case of a conflict between the provisions set forth above and the Statement of Work, the Proposal or any other attachment to this Agreement, the provisions set forth above will take precedence and govern, and the order of precedence thereafter shall be the provisions in (i) the Statement of Work; (ii) the Proposal; and (iii) any other attachment to the Agreement.

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be signed by its duly authorized representative on the date indicated below:

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Signature:__________________________
Printed Name:_______________________
Title:______________________________
Date:______________________________

SERVICE PROVIDER

Signature:__________________________
Printed Name:_______________________
Title:______________________________
Date:______________________________