<table>
<thead>
<tr>
<th><strong>1. CONTRACT NO.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>HHSN2722017000351</td>
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<table>
<thead>
<tr>
<th><strong>2. TASK ORDER NO.</strong></th>
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<tbody>
<tr>
<td>75N93020F00003</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>3. REQUISITION NO.</strong></th>
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</thead>
<tbody>
<tr>
<td>5824798</td>
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<table>
<thead>
<tr>
<th><strong>4(A). TASK ORDER AWARD DATE</strong></th>
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</thead>
<tbody>
<tr>
<td>See Block 13C</td>
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<table>
<thead>
<tr>
<th><strong>4(B). TASK ORDER EFFECTIVE DATE</strong></th>
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</thead>
<tbody>
<tr>
<td>See Block 13(C)</td>
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</table>

<table>
<thead>
<tr>
<th><strong>4(C). TASK ORDER COMPLETION DATE</strong></th>
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<tr>
<td>January 15, 2022</td>
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<table>
<thead>
<tr>
<th><strong>5(A). AWARD AUTHORITY</strong></th>
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<tr>
<td>(Pursuant to FAR 16.505, 41 USC 253)</td>
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<table>
<thead>
<tr>
<th><strong>5(B). TYPE OF ORDER</strong></th>
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</thead>
<tbody>
<tr>
<td>[X] Cost Reimbursement</td>
</tr>
<tr>
<td>[ ] Firm Fixed Price</td>
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</table>

<table>
<thead>
<tr>
<th><strong>6. ISSUING OFFICE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Address correspondence to)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>7. ADMINISTRATIVE OFFICE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(if different from block No. 6):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>8. CONTRACTOR</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Name, address and ZIP code)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>9. CONTRACTING OFFICER'S REPRESENTATIVE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Name, office code, and telephone number)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>10(A). ACCOUNTING AND APPROPRIATION DATA</strong></th>
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<tbody>
<tr>
<td>FY 20</td>
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</table>

<table>
<thead>
<tr>
<th><strong>10(B). FUNDING THIS ACTION</strong></th>
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</thead>
<tbody>
<tr>
<td>$424,455</td>
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</table>

<table>
<thead>
<tr>
<th><strong>10(C). TASK ORDER VALUE</strong></th>
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<tbody>
<tr>
<td>$424,455</td>
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</table>

<table>
<thead>
<tr>
<th><strong>11. DESCRIPTION OF SERVICES (Scope of Work):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE: To issue Task C12 for “Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>12(A). NAME &amp; TITLE OF SIGNER (Typed)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicholas Hinson - Contract Manager</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>13(A). CONTRACTING OFFICER NAME (Typed)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Miranda Adams</td>
</tr>
<tr>
<td>OA, DEA, NIAID, NIH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>12(B). Signature</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>[Signature]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>12(C). DATE</strong></th>
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</thead>
<tbody>
<tr>
<td>9/14/2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>13(B). Signature</strong></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th><strong>13(C). DATE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>9/15/2020</td>
</tr>
</tbody>
</table>
The subject Task Order, 75N93020F00003 (Task C12) is issued in accordance with the terms and conditions of the NIAID Preclinical Models of Infectious Diseases IDIQ base contract HHSN272201700035I. In addition to the terms and conditions described herein, the terms and conditions of the base contract shall be considered to apply to this Task Order.

SECTION B – SERVICES AND COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES
In accordance with Attachment 1, Statement of Work, The Contractor shall evaluate Proprietary Info in dogs. The secondary purpose is to determine whether Proprietary Info in dogs can Proprietary Info. The third objective is to Proprietary Info will be provided by a third party NIAID designee.

ARTICLE B.2. ESTIMATED COST

a. The estimated cost of the Base Period of this Task Order is $424,455.

ARTICLE B.3. ADVANCED UNDERSTANDINGS

1. Contract Number Designation
On all correspondence submitted under this task order, the Contractor agrees to clearly identify the contract number, task order number and task that appear on the face page of the contract as follows:
   
   Contract Number: HHSN272201700035I
   Task Order Number: 75N93020F00003
   Task: C12

2. Invoices
On all invoices for payment submitted under this task order, the Contractor agrees to clearly identify the contract number, task order number and task that appear on the contract face page as follows:

   Contract Number: HHSN272201700035I
   Task Order Number: 75N93020F00003
   Task: C12

3. Indirect Costs
In no event, shall the final amount reimbursable for fringe and facilities and administrative costs exceed the provisional or final ceilings established in the negotiated Indirect Rate Agreement.

4. Subcontract
To negotiate a cost-reimbursement type subcontract with Subcontractor Info for an amount not to exceed the following:
SECTION C – STATEMENT OF WORK

ARTICLE C.1. STATEMENT OF WORK AND TECHNICAL REPORTING REQUIREMENTS
Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work (Attachment 1), Delivery Schedule (Attachment 2), and Reporting Requirements (Attachment 3), attached hereto and made a part of this Task Order.

ARTICLE C.2. REPORTING REQUIREMENTS
All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via eRDS, available at the following website: https://erds.niaid.nih.gov/.
All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

SECTION D – PACKAGING, MARKING AND SHIPPING
No additional requirements beyond those of the base contract.

SECTION E – INSPECTION AND ACCEPTANCE
No additional requirements beyond those of the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. TASK ORDER COMPLETION PERIOD
a. The completion date of this task order shall be January 15, 2022.

SECTION G – CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER REPRESENTATIVE (COR)
The following COR will represent the Government for the purpose of this Task Order:

Primary COR: Julio Aliberti  
5601 Fishers Lane, Rockville Room 8A27, MD 20852  
Telephone: 301-761-7322  
E-Mail: julio.aliberti@nih.gov

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this task order; (5) assisting in the resolution of technical problems encountered during performance.
The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement’s skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than 30 days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individual is considered to be essential to the work being performed hereunder:

<table>
<thead>
<tr>
<th>NAME</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrew Moorhead, DVM, MS, Ph.D., DACVM</td>
<td>Principal Investigator (PI)</td>
</tr>
<tr>
<td>Michael Dzimianski, DVM, MS</td>
<td>Co-Principal Investigator (Co-Pl)</td>
</tr>
</tbody>
</table>

SECTION H – SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1 CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.12.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under
this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer’s written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor’s name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: [http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare](http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare)).

ARTICLE H.2 ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: [http://grants1.nih.gov/grants/olaw/references/phspol.htm](http://grants1.nih.gov/grants/olaw/references/phspol.htm)

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor’s technical proposal, which is incorporated by reference.

SECTION I – CONTRACT CLAUSES

In addition to those clauses contained in Base Contract No. HHSN272201700035I, the following clauses apply to this cost-reimbursement task order contract:

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: [http://www.acquisition.gov/far/](http://www.acquisition.gov/far/), HHSAR Clauses at: [http://www.hhs.gov/policies/hhsar/subpart352.html](http://www.hhs.gov/policies/hhsar/subpart352.html).

<table>
<thead>
<tr>
<th>FAR CLAUSE NO.</th>
<th>DATE</th>
<th>TITLE</th>
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<tr>
<td>52.202-1</td>
<td>Nov 2013</td>
<td>Definitions (Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.203-3</td>
<td>Apr 1984</td>
<td>Gratuities (Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.203-5</td>
<td>May 2014</td>
<td>Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.203-6</td>
<td>Sep 2006</td>
<td>Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.203-7</td>
<td>May 2014</td>
<td>Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.203-8</td>
<td>May 2014</td>
<td>Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)</td>
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<td>52.203-10</td>
<td>May 2014</td>
<td>Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)</td>
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<td>52.203-12</td>
<td>Oct 2010</td>
<td>Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)</td>
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<tr>
<td>CLAUSE NO.</td>
<td>DATE</td>
<td>TITLE</td>
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<tr>
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<tr>
<td>52.203-17</td>
<td>Apr 2014</td>
<td>Contractor Employee Whistleblower Rights and Requirements to Inform</td>
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<td>Employees of Whistleblower Rights (Over the Simplified Acquisition</td>
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<td></td>
<td></td>
<td>Threshold)</td>
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<td>52.203-99</td>
<td>Feb 2015</td>
<td>Prohibition on Contracting with Entities That Require Certain Internal</td>
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<td>Confidentiality Agreements (DEVICATION)</td>
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<td>52.204-4</td>
<td>May 2011</td>
<td>Printed or Copied Double-Sided on Postconsumer Fiber Content Paper</td>
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<td>(Over the Simplified Acquisition Threshold)</td>
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<td>52.204-10</td>
<td>Oct 2016</td>
<td>Reporting Executive Compensation and First-Tier Subcontract Awards</td>
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<td></td>
<td>($30,000 or more)</td>
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<td>52.204-13</td>
<td>Oct 2016</td>
<td>System for Award Management Maintenance</td>
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<tr>
<td>52.209-6</td>
<td>Oct 2015</td>
<td>Protecting the Government's Interest When Subcontracting With</td>
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<tr>
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<td></td>
<td>Contractors Debarred, Suspended, or Proposed for Debarment (Over</td>
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<td></td>
<td></td>
<td>$35,000)</td>
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<tr>
<td>52.215-2</td>
<td>Oct 2010</td>
<td>Audit and Records - Negotiation [Note: Applies to ALL contracts funded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in whole or in part with Recovery Act funds, regardless of dollar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>value, AND contracts over the Simplified Acquisition Threshold</td>
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<tr>
<td></td>
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<td>funded exclusively with non-Recovery Act funds.], Alternate II (Aug</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2016)</td>
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<td>52.215-8</td>
<td>Oct 1997</td>
<td>Order of Precedence - Uniform Contract Format</td>
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<td>52.215-10</td>
<td>Aug 2011</td>
<td>Price Reduction for Defective Certified Cost or Pricing Data (Over</td>
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<td></td>
<td>$750,000)</td>
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<td>52.215-12</td>
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<td>Subcontractor Cost or Pricing Data (Over $750,000)</td>
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<td>52.215-14</td>
<td>Oct 2010</td>
<td>Integrity of Unit Prices (Over the Simplified Acquisition Threshold)</td>
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<td>52.215-15</td>
<td>Oct 2010</td>
<td>Pension Adjustments and Asset Reversions (Over $750,000)</td>
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<tr>
<td>52.215-18</td>
<td>Jul 2005</td>
<td>Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB)</td>
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<td></td>
<td>other than Pensions</td>
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<td>52.215-19</td>
<td>Oct 1997</td>
<td>Notification of Ownership Changes</td>
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<td>52.215-21</td>
<td>Oct 2010</td>
<td>Requirements for Certified Cost or Pricing Data and Data Other Than</td>
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<td></td>
<td></td>
<td>Certified Cost or Pricing Data - Modifications</td>
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<td>52.215-23</td>
<td>Oct 2009</td>
<td>Limitations on Pass-Through Charges (Over the Simplified Acquisition</td>
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<tr>
<td></td>
<td></td>
<td>Threshold)</td>
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<td>52.216-7</td>
<td>Jun 2013</td>
<td>Allowable Cost and Payment, Alternate II (Aug 2012)</td>
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<tr>
<td>52.216-11</td>
<td>Apr 1984</td>
<td>Cost Contract - No Fee</td>
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<tr>
<td>52.219-8</td>
<td>Nov 2016</td>
<td>Utilization of Small Business Concerns (Over the Simplified Acquisition</td>
</tr>
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<td></td>
<td></td>
<td>Threshold)</td>
</tr>
<tr>
<td>52.219-9</td>
<td>Jan 2017</td>
<td>Small Business Subcontracting Plan (Over $700,000, $1.5 million for</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Construction)</td>
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<tr>
<td>52.219-16</td>
<td>Jan 1999</td>
<td>Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for Construction)</td>
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<td>52.222-2</td>
<td>Jul 1990</td>
<td>Payment for Overtime Premium (Over the Simplified Acquisition</td>
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<tr>
<td></td>
<td></td>
<td>Threshold) (Note: The dollar amount in paragraph (a) of this clause is</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$0 unless otherwise specified in the contract.)</td>
</tr>
<tr>
<td>52.222-3</td>
<td>Jun 2003</td>
<td>Convict Labor</td>
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<tr>
<td>52.222-21</td>
<td>Apr 2015</td>
<td>Prohibition of Segregated Facilities</td>
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<tr>
<td>52.222-26</td>
<td>Sep 2016</td>
<td>Equal Opportunity</td>
</tr>
<tr>
<td>52.222-35</td>
<td>Oct 2015</td>
<td>Equal Opportunity for Veterans ($150,000 or more)</td>
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<tr>
<td>52.222-36</td>
<td>Jul 2014</td>
<td>Equal Opportunity for Workers with Disabilities</td>
</tr>
<tr>
<td>52.222-37</td>
<td>Feb 2016</td>
<td>Employment Reports on Veterans ($150,000 or more)</td>
</tr>
<tr>
<td>52.222-40</td>
<td>Dec 2010</td>
<td>Notification of Employee Rights Under the National Labor Relations Act</td>
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<td></td>
<td></td>
<td>(Over the Simplified Acquisition Threshold)</td>
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<tr>
<td>52.222-50</td>
<td>Mar 2015</td>
<td>Combating Trafficking in Persons</td>
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</table>
**FAR DATE TITLE**

<table>
<thead>
<tr>
<th>CLAUSE NO.</th>
<th>DATE</th>
<th>TITLE</th>
</tr>
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<tr>
<td>52.222-54</td>
<td>Oct 2015</td>
<td>Employment Eligibility Verification (Over the Simplified Acquisition Threshold)</td>
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<td>52.223-6</td>
<td>May 2001</td>
<td>Drug-Free Workplace</td>
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<tr>
<td>52.223-18</td>
<td>Aug 2011</td>
<td>Encouraging Contractor Policies to Ban Text Messaging While Driving</td>
</tr>
<tr>
<td>52.225-1</td>
<td>May 2014</td>
<td>Buy American - Supplies</td>
</tr>
<tr>
<td>52.225-13</td>
<td>Jun 2008</td>
<td>Restrictions on Certain Foreign Purchases</td>
</tr>
<tr>
<td>52.227-2</td>
<td>Dec 2007</td>
<td>Notice and Assistance Regarding Patent and Copyright Infringement</td>
</tr>
<tr>
<td>52.227-11</td>
<td>May 2014</td>
<td>Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.</td>
</tr>
<tr>
<td>52.227-14</td>
<td>Dec 2007</td>
<td>Rights in Data - General, Alternate IV (Dec 2007)</td>
</tr>
<tr>
<td>52.232-9</td>
<td>Apr 1984</td>
<td>Limitation on Withholding of Payments</td>
</tr>
<tr>
<td>52.232-20</td>
<td>Apr 1984</td>
<td>Limitation of Cost</td>
</tr>
<tr>
<td>52.232-23</td>
<td>May 2014</td>
<td>Assignment of Claims</td>
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<td>52.232-25</td>
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<td>Prompt Payment, Alternate I (Feb 2002)</td>
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<td>52.232-33</td>
<td>Jul 2013</td>
<td>Payment by Electronic Funds Transfer--System for Award Management</td>
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<td>52.232-39</td>
<td>Jun 2013</td>
<td>Unenforceability of Unauthorized Obligations</td>
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<td>52.233-1</td>
<td>May 2014</td>
<td>Disputes</td>
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<tr>
<td>52.233-3</td>
<td>Aug 1996</td>
<td>Protest After Award, Alternate I (Jun 1985)</td>
</tr>
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<td>52.233-4</td>
<td>Oct 2004</td>
<td>Applicable Law for Breach of Contract Claim</td>
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<td>52.242-1</td>
<td>Apr 1984</td>
<td>Notice of Intent to Disallow Costs</td>
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<td>Jan 1997</td>
<td>Certification of Final Indirect Costs</td>
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<td>Jul 1995</td>
<td>Bankruptcy (Over the Simplified Acquisition Threshold)</td>
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<td>Oct 2010</td>
<td>Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)</td>
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<td>Dec 1996</td>
<td>Competition in Subcontracting (Over the Simplified Acquisition Threshold)</td>
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<td>Subcontracts for Commercial Items</td>
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<td>Government Property, Alternate II (April 2012)</td>
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<td>52.245-9</td>
<td>Apr 2012</td>
<td>Use and Charges</td>
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<td>Limitation of Liability (Over the Simplified Acquisition Threshold)</td>
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<td>52.249-6</td>
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<td>Termination (Cost-Reimbursement)</td>
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<td>52.249-14</td>
<td>Apr 1984</td>
<td>Excusable Delays</td>
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<td>52.253-1</td>
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**HHSAR DATE TITLE**

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<tr>
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<th>DATE</th>
<th>TITLE</th>
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<td>Dec 2015</td>
<td>Anti-Lobbying</td>
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<td>352.222-70</td>
<td>Dec 2015</td>
<td>Contractor Cooperation in Equal Employment Opportunity Investigations</td>
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<td>352.227-70</td>
<td>Dec 2015</td>
<td>Publications and Publicity</td>
</tr>
<tr>
<td>352.233-71</td>
<td>Dec 2015</td>
<td>Litigation and Claims</td>
</tr>
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<td>352.237-75</td>
<td>Dec 2015</td>
<td>Key Personnel</td>
</tr>
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</table>

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT W_EDUCATIONAL INSTITUTION- Rev. 11/2017].
ARTICLE 1.2. AUTHORIZED SUBSTITUTION OF CLAUSES

No additional clauses beyond those of the base contract.

ARTICLE 1.3. ADDITIONAL FAR CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

1. HHSAR Clause 352.231-70, Salary Rate Limitation (December 2015)
   Note: The Salary Rate Limitation is at the Executive Level II Rate.
   See the following website for Executive Schedule rates of pay:
   (For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay
   for the Executive Schedule. For prior year rates, click on Salaries and Wages/select
   Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive
   Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

ARTICLE 1.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

1. 52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (DEC 2019)

The Offeror shall not complete the representation in this provision if the Offeror has represented that it “does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument” in the provision at 52.204-26, Covered Telecommunications Equipment or Services—Representation, or in paragraph (v) of the provision at 52.212-3, Offeror Representations and Certifications—Commercial Items.

   (a) Definitions. As used in this provision—

   “Covered telecommunications equipment or services”, “critical technology”, and “substantial or essential component” have the meanings provided in clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

   (b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Contractors are not prohibited from providing—

   (1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or
(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) ([https://www.sam.gov](https://www.sam.gov)) for entities excluded from receiving federal awards for “covered telecommunications equipment or services”.

(d) Representation. The Offeror represents that it □ will, □ will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation.

(e) Disclosures. If the Offeror has represented in paragraph (d) of this provision that it “will” provide covered telecommunications equipment or services”, the Offeror shall provide the following information as part of the offer—

1. A description of all covered telecommunications equipment and services offered (include brand; model number, such as original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

2. Explanation of the proposed use of covered telecommunications equipment and services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b) of this provision;

3. For services, the entity providing the covered telecommunications services (include entity name, unique entity identifier, and Commercial and Government Entity (CAGE) code, if known); and

4. For equipment, the entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).

(End of provision)

2. FAR Clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (August 2020).

(a) Definitions. As used in this clause—

Covered foreign country means The People’s Republic of China.

Covered telecommunications equipment or services means—

1. Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

2. For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou.
Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means—

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled—

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or


Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of
any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this
clause applies or the covered telecommunication equipment or services are covered by a waiver
described in Federal Acquisition Regulation 4.2104.

(c) Exceptions. This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or
interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or
permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services
used as a substantial or essential component of any system, or as critical technology as part of any
system, during contract performance, or the Contractor is notified of such by a subcontractor at any
tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this
clause to the Contracting Officer, unless elsewhere in this contract are established procedures for
reporting the information; in the case of the Department of Defense, the Contractor shall report to the
website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the
Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected
order or, in the case of the Department of Defense, identify both the indefinite delivery contract and
any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of
this clause

(i) Within one business day from the date of such identification or notification: the
contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if
known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number
(original equipment manufacturer number, manufacturer part number, or wholesaler number); item
description; and any readily available information about mitigation actions undertaken or
recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this
clause: any further available information about mitigation actions undertaken or recommended. In
addition, the Contractor shall describe the efforts it undertook to prevent use or submission of
covered telecommunications equipment or services, and any additional efforts that will be
incorporated to prevent future use or submission of covered telecommunications equipment or
services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph
(e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of
commercial items.

(End of clause)

2. FAR 52.204-26, Covered Telecommunications Equipment or Services-Representation (Dec 2019).
(a) Definitions. As used in this provision, “covered telecommunications equipment or services” has the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for “covered telecommunications equipment or services”.

(c) Representation. The Offeror represents that it ☐ does, ☐ does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(End of clause)

SECTION J – LIST OF ATTACHMENTS
The following documents are attached and incorporated in this task order:
1. Statement of Work, 3 pages
2. Reporting Requirements, 2 pages
3. Delivery Schedule, 1 page
PRECLINICAL MODELS OF INFECTIOUS DISEASES

Task C12
Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs
STATEMENT OF WORK

BACKGROUND

The primary objectives of this Task Order are to evaluate Proprietary Info infection in dogs. The secondary purpose is to determine whether Proprietary Info dogs can also Proprietary Info. The third objective is to

Task Order C-12 - Enclosure 1
Statement of Work

Obtained via FOIA by White Coat Waste Project
REQUIREMENTS

Indepenedly, and not as an agent of the Government, the Contractor shall furnish on its own or through a subcontractor all the necessary services, qualified personnel, materials, equipment, and facilities needed to perform the Statement of Work. The contractor shall include all anticipated expenses related to Review and selection of subcontractors shall be conducted in compliance with FAR Clause 52.244-2.

Subtask 1: Study Protocol
1. The Contractor shall develop a study protocol for Proprietary Info in dogs.
2. The Contractor shall initiate work only after approval of the study protocol is communicated in writing by the NIAID COR.

Subtask 2: Acquisition of Animals and Proprietary Info
1. The Contractor shall acquire healthy, adult beagle dogs from a USDA Class A licensed source.

Subtask 3: Animal Groups Proprietary Info and In-life Study
1. The Contractor shall administer different formulations Proprietary Info to dogs via the intramuscular route in accordance with the approved study protocol. Animals will receive a total of three doses Proprietary Info or control on day 0, 28, and 56;
2. One month after the last Proprietary Info the Contractor shall challenge animals Proprietary Info.
3. The Contractor shall monitor animal health twice per day.
4. The Contractor shall collect and process blood and urine samples from dogs for the evaluation of Proprietary Info.

Subtask 4: Evaluation of Proprietary Info
1. Evaluation of whole blood for the presence Proprietary Info.
2. Evaluation by in vitro Proprietary Info assay of the Proprietary Info.

Subtask 5: Evaluation of Proprietary Info
1. The Contractor shall perform Proprietary Info assessments to determine the type of responses elicited by Proprietary Info.
Subtask 6: Evaluation of Safety and Tolerability

The Contractor shall conduct safety and tolerability assessment of the animals by:

1. Weekly standard physical examination by veterinarian including routine cage site observations and local reaction to 
2. Collecting blood and urine and conducting blood and urine analysis (IDEXX, CBC, Urinalysis).
In addition to those reports required by the other terms of this order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with Deliveries of this order:

1. **Study Protocol**
   The Contractor shall design and draft a protocol for the Lymphatic Filariasis Vaccine Efficacy Trial in dogs. The contractor shall submit the draft protocol for review to the COR within 15 days after award. The COR will review the draft study protocol report and provide the Contractor with comments and revisions. The Contractor will submit the final study protocol report within 30 days after award for approval by the COR and conduct the study accordingly.

2. **Monthly Progress Reports**
   The Contractor shall submit electronic copies of the Monthly Report to the Contracting Officer’s Representative (COR) and to the Contracting Officer via eRDS. The first reporting period consists of the first full month of performance and any fractional part of the initial month. Thereafter, each report shall consist of a full month of performance. If any of the studies are conducted by a subcontractor, such studies should be identified and included as an attachment.
   Each progress report shall include:
   1. A title page containing:
      - Contract number
      - Task order number and title
      - Period of performance being reported
      - Contractor’s name and address
      - Date of report submission
      - A notation to indicate whether the report includes a final study report.
   2. Progress on all subtasks/milestones
   3. Gantt chart to capture updates to the task order schedule.
   4. Accomplishments to date, including supporting data;
   5. Description of any technical or performance problems, along with proposed corrective action
   6. Update of expenditures including budget variances.

3. **Draft and Final Study Report**
   The Contractor shall prepare and submit a draft report on the Lymphatic Filariasis Vaccine Efficacy Trial within 4 weeks from the conclusion of the study. The COR will review the draft report and provide the Contracting Officer with comments and notice of which raw data are to be included in the Final Study Report within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary, and the final version submitted as specified in the Delivery Schedule. This report shall include:
   1. Title page containing:
      - Contract number
      - Task order number and title
      - Contractor name and address
• Study title and number
• Study start and end dates
• Date of report submission

2. Abstract, keywords, and Introduction covering the purpose and scope of the task order

3. Separate sections for (list the sub-studies) Materials and the Methods (including the
   operating procedure used), Results, (i.e., pertinent primary and summarized data in tables or
   graphs as appropriate to present significant results achieved), Discussion, Conclusions
   (resulting from analysis, and refinements employed during the refinement of the final
   method), and References. The report shall summarize all the salient findings from the study
   and include the following:
   • Proprietary info results for its Proprietary info including statistical analysis;
   • Proprietary info results for its Proprietary info
   • Proprietary info results for its Proprietary info
   • Proprietary info results for its Proprietary info
   • Proprietary info data including Proprietary info responses;
   • Proprietary info safety assessment including local reaction at sites of injection, any abnormal
     clinical observation, clinical chemistry, and urinalysis findings.

4. Copies of any abstracts, poster presentations, manuscripts, and publications
5. Copies of raw data as requested by the COR
6. E-data Set (and delivery method of all associated data)
7. List of references of the testing procedures used in the execution of the protocol.
8. The approved study protocol appended in its entirety, including any amendments or deviations.

4. Teleconference Minutes
   A. Monthly Teleconference - The contractor shall provide agenda a week before the teleconference,
      and teleconference minutes from each teleconference pertaining to this task order within 7 days of the
      teleconference.
   B. Ad Hoc Teleconference: The contractor shall provide minutes from each teleconference pertaining
      to this task order within 7 days of the teleconference.

***NOTE: The Contractor shall include, in any technical progress report submitted, the applicable PubMed
Central (PMC) or NIH Manuscript Submission reference number when citing publication that arise from its
NIH funded research.

Obtained via FOIA by White Coat Waste Project
Satisfactory performance of the task order shall be deemed to occur upon completion of the work described in the Statement of Work of this task order and upon delivery and acceptance by the Contracting Officer, or duly authorized representative, of the following items specified below and as described in the Statement of Work and in the Reporting Requirements of this order.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Reference</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Draft Study protocol</td>
<td>Reporting Requirements, 1</td>
<td>Within 15 days following task order award</td>
</tr>
<tr>
<td>2</td>
<td>Final Study Protocol</td>
<td>Reporting Requirements, 1</td>
<td>Within 30 days following task order award</td>
</tr>
<tr>
<td>3</td>
<td>Monthly Progress Reports</td>
<td>Reporting Requirements, 2</td>
<td>On or before the 15th day of the month following the reporting period</td>
</tr>
<tr>
<td>4</td>
<td>Draft Study Report</td>
<td>Reporting Requirements, 3</td>
<td>Within 30 days of task order expiration</td>
</tr>
<tr>
<td>5</td>
<td>Final Study Report</td>
<td>Reporting Requirements, 3</td>
<td>On or before task order expiration</td>
</tr>
<tr>
<td>6</td>
<td>Teleconference Minutes</td>
<td>Reporting Requirements, 4</td>
<td>On or before 7 days following each teleconference</td>
</tr>
</tbody>
</table>

The above items shall be addressed and delivered to:

<table>
<thead>
<tr>
<th>Addressee</th>
<th>Deliverable Item(s) No</th>
<th>Quantity and Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracting Officer and Contracting Officer's Representative, NIAID</td>
<td>2, 3, 5, 6</td>
<td>1 electronic copy (pdf) submitted via eRDS</td>
</tr>
<tr>
<td>Contracting Officer’s Representative, NIAID</td>
<td>1, 4</td>
<td>1 electronic copy (pdf) submitted via email</td>
</tr>
</tbody>
</table>

Obtained via FOIA by White Coat Waste Project
STUDY PROTOCOL

I. Objectives/Scope
The contractor shall evaluate the Propnetary Info in dogs, determine whether Propnetary Info samples from the Propnetary Info dogs can also Propnetary Info in the dog model of Propnetary Info and evaluate the general safety Propnetary Info.

II. Approach
A. Overview: Dogs will be Propnetary Info in groups as outlined in Table 1. They will then be challenged on day 84 post-initial Propnetary Info. Animals will be euthanized after day 196 and Propnetary Info determined. The complete study timeline is detailed in Table 2.

Each set of experiments will use 14 dogs, which will total 28 dogs at completion of the study (7 dogs in each group. The power calculation to justify the number of animals per group to reach statistical significance is displayed in Table 3.

<table>
<thead>
<tr>
<th>Table 1: Animal Groups and Propnetary Info (Blinded Propnetary Info) will be shipped as A, B, C, D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
</tbody>
</table>

Second set of experiments:

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Propnetary Info</th>
<th>Propnetary Info (Day)</th>
<th>Propnetary Info subcutaneous (Day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>3</td>
<td>blinded</td>
<td>0, 28, 56</td>
<td>84</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>blinded</td>
<td>0, 28, 56</td>
<td>84</td>
</tr>
<tr>
<td>C</td>
<td>3</td>
<td>blinded</td>
<td>0, 28, 56</td>
<td>84</td>
</tr>
<tr>
<td>D</td>
<td>4</td>
<td>blinded</td>
<td>0, 28, 56</td>
<td>84</td>
</tr>
</tbody>
</table>
Table 2: Sample Collection

Outlined below is a suggested plan for sample collection and processing. This can be modified as needed to meet the objectives of the study, including

<table>
<thead>
<tr>
<th>Day</th>
<th>Sample</th>
<th>Volume &amp; Processing</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1</td>
<td>Blood</td>
<td>30 ml (10 ml for sera, 20ml for PBMC)</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>-1</td>
<td>Blood</td>
<td>5 ml whole blood</td>
<td>Clinical chemistry</td>
</tr>
<tr>
<td>-1</td>
<td>Urine</td>
<td>N/A</td>
<td>Urinalysis</td>
</tr>
<tr>
<td>27</td>
<td>Blood</td>
<td>30 ml (10 ml for sera, 20ml for PBMC)</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>55</td>
<td>Blood</td>
<td>30 ml (10 ml for sera, 20ml for PBMC)</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>77</td>
<td>Blood</td>
<td>20 ml (for sera)</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>83</td>
<td>Blood</td>
<td>20 ml (20ml for PBMC)</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>83</td>
<td>Blood</td>
<td>5 ml whole blood</td>
<td>Clinical chemistry</td>
</tr>
<tr>
<td>83</td>
<td>Urine</td>
<td>N/A</td>
<td>Urinalysis</td>
</tr>
<tr>
<td>168</td>
<td>Blood</td>
<td>Whole blood 10 ml EDTA</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>182</td>
<td>Blood</td>
<td>Whole blood 10 ml EDTA</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>197</td>
<td>Blood</td>
<td>Whole blood 10 ml EDTA</td>
<td>Proprietary Info</td>
</tr>
<tr>
<td>197</td>
<td>Blood</td>
<td>30 ml (10 ml for sera, 20ml for PBMC)</td>
<td>Proprietary Info</td>
</tr>
</tbody>
</table>

Table 3: Power Calculation

<table>
<thead>
<tr>
<th>Tests</th>
<th>ANOVA: Fixed effects, omnibus, one-way</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis</td>
<td>Post hoc: Compute achieved power</td>
</tr>
<tr>
<td>Input: Effect size f</td>
<td>= 1.25</td>
</tr>
<tr>
<td>α err prob</td>
<td>= 0.05</td>
</tr>
<tr>
<td>Total sample size</td>
<td>= 14</td>
</tr>
<tr>
<td>Number of groups</td>
<td>= 4</td>
</tr>
<tr>
<td>Output: Noncentrality parameter λ</td>
<td>= 21.8750000</td>
</tr>
<tr>
<td>Critical F</td>
<td>= 3.7082648</td>
</tr>
<tr>
<td>Numerator df</td>
<td>= 3</td>
</tr>
<tr>
<td>Denominator df</td>
<td>= 10</td>
</tr>
<tr>
<td>Power (1-β err prob)</td>
<td>= 0.9087456</td>
</tr>
</tbody>
</table>
B. Outline of general work plan and time to perform animal experiments:

These experiments will be conducted in conjunction with the Filariasis Research Reagent Resource Center (FR3) housed at UGA-CVM. To prevent redundancy, the methods we plan to use are provided in the Methods section below. We stress that the methods and protocols used for infection and sample collection have been used by the FR3 for approximately 40 years.

Our approach in this contract is to use these standardized methods and to employ highly experienced and skilled scientists to carry out the proposed work. It is important to note that a great deal of technical skill and expertise is required to have these methods function efficiently. We have in place an experienced group of scientists who can accomplish these goals, and all the necessary facilities are available at UGA. Therefore, if we are awarded the contract, we will be able to start the project on DAY ONE without any delay and complete successfully within the proposed time frame.

C. Outline of general work plan and time to perform serum analysis:

The analysis will take place concurrently with animal experiments as outlined above and will be completed within the desired time frame.

III. Materials and Methods (Animal experiments)

A. Materials:

1. Proprietary Info

2. Test articles:

   Obtained from the third party NIAID site.

3. Canines:

   Pathogen-free adult beagle dogs will be obtained from an AAALAC-approved USDA Class A licensed source (see below under methods).

4. Disposables/Supplies: Syringes, needles, blood collection tubes, etc. will be obtained from standard UGA-approved vendors.

B. Methods:

1. Screening of dogs

   Upon arrival of dogs from vendor, they will be allowed to acclimate for 7 days per UGA IACUC policy. After the acclimation period, dogs will be screened using a standard test kit per manufacturer’s instructions. Also, dogs will be screened for Proprietary Info and negative for Proprietary Info will be enrolled in the study. The screening will be performed in the PI’s laboratory.

2. Challenges

   Will be prepared according to the Proprietary Info instructions and will be administered by intramuscular injection with a low dead-space syringe and 22-Ga 1 ½” needle to maximize the amount of Proprietary Info injected.

   Following Proprietary Info methods will be used. Following Proprietary Info determined by screening for Proprietary Info using standard diagnostic tests. All these methods are already established and are routinely performed in the PI’s laboratory at UGA.
4. Blood and Urine collection:
Veterinarians and technical staff will collect blood by venipuncture of the jugular vein on the schedule according to Table 2. Blood samples will either be submitted to UGA’s Clinical Pathology Laboratory for complete blood count and evaluated blood samples and serum isolated will be shipped to the subcontractor. Blood samples and serum isolated will be shipped to the subcontractor according to Table 2. Protein amounts will be qualitatively evaluated using semi-quantitative colorimetric urine reagent strips in accordance with manufacturer’s instructions.

5. Physical Exams/Documentation of Clinical Signs:
Weekly physical exams will be performed by veterinarians in order to evaluate clinical parameters, including those indicative of vaccine reactions, including, but not limited to:
- Muscular pain
- Fever
- Lethargy
- Abnormal behavior
- Swelling of lymph nodes
- Upper respiratory tract hypersensitivity
- Skin rashes, in particular at the site of vaccination or challenge
- Gastrointestinal symptoms
- Neurological symptoms
- Lymphedema proximal to site

Results of Physical Exams and clinical observations will be recorded.

6. Shipping:
Proprietary Info will be shipped to the site and subcontractor in thermoregulated shipping containers overnight using a standard freight carrier with documented tracking methods. The provider and subcontractor will provide instructions on packaging.

IV. Materials and Methods (Serum Analysis)
A. Evaluating the responses:

B. Functional analysis of cells:

C. Evaluation of responses:
Contract Number: HHSN272201700035I

Task Order Number: 75N93020F00003

Task: C12

Title: Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

Period of performance: September 29, 2020 to October 25, 2020

Contractor: University of Georgia
College of Veterinary Medicine
Department of Infectious Diseases
501 D.W. Brooks Drive
Athens, GA 30602

Due Date: October 25, 2020
The following is the report for the month of October with the reporting period ending October 25, 2020.

Progress for this month was documented in the minutes of the conference call with the COR, Dr. Julio Aliberti.

The call occurred on Thursday Oct. 15, 2020 at 10 am Eastern.

The following items were discussed.

1. eRDS access:
The contract is not visible in eRDS. Andy Moorhead will email John Outen directly. This will allow submission of deliverables, including the final study protocol, which was approved in a previous email.

2. Starting experiments:
   a. Dogs: UGA wishes to order dogs for arrival early November, in order to allow acclimation (7 days mandated) prior to the expected start date of mid-November.

   b. Proprietary info: Julio Aliberti has been in touch with who will provide the materials directly to UGA

3. Next conference call:
Andy Moorhead will contact Julio Aliberti by email on Friday the 13th to update him on the status of the project.
Contract Number: HHSN272201700035I

Task Order Number: 75N93020F00003

Task: C12

Title: Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

Period of performance: October 26, 2020 to November 25, 2020

Contractor: University of Georgia
College of Veterinary Medicine
Department of Infectious Diseases
501 D.W. Brooks Drive
Athens, GA 30602

Due Date: November 25, 2020
The following is the report for the month of November with the reporting period ending November 25, 2020.

Progress for this month was documented in the minutes of the conference call with the COR, Dr. Julio Aliberti, and under the heading PROGRESS.

I. CONFERENCE CALL
   A. Nov. 13-2 PM Eastern via Zoom:
      Attendees: Julio Aliberti, Andy Moorhead, Elyssa Campbell
      - Dogs arrived for Phase 1 of study. Study to commence Nov. 19 when the mandated 7-day acclimation period is over.
      - Julio informed that there would be a potential delay in [Proprietary Info] if a delay occurs, the study will start Dec. 10.
      - A call will be scheduled for 4 PM Eastern on Nov. 18th to update UGA.

   B. Nov. 18-4 PM Eastern via phone:
      Attendees: Julio Aliberti, Elyssa Campbell
      [Proprietary Info] will be shipped today for arrival by 9 am Eastern on Nov. 19th. Andy Moorhead will be notified by email at the time of shipment, and will inform Elyssa Campbell as soon as he receives the email.

II. PROGRESS
    Dogs arrived at UGA on Nov. 12. The study started on Nov. 19 after the 7-day mandated acclimation period. Physical exams were performed, CBC/chemistry was performed, urine collected, and serum and blood was shipped to [Subcontractor] (subcontractor) [Proprietary Info] were prepared and administered according to instructions provided by the [Proprietary Info] producer. Animals were allocated in a random-block design.
Contract Number: HHSN272201700035I

Task Order Number: 75N93020F00003

Task: C12

Title: Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

Period of performance: November 26, 2020 to December 25, 2020

Contractor: University of Georgia
College of Veterinary Medicine
Department of Infectious Diseases
501 D.W. Brooks Drive
Athens, GA 30602

Due Date: December 25, 2020

Obtained via FOIA by White Coat Waste Project
The following is the report for the month of December with the reporting period ending December 25, 2020.

Progress for this month is documented in a progress email with the COR, Dr. Julio Aliberti, and under the heading PROGRESS.

I. UPDATE EMAIL (IN LIEU OF CONFERENCE CALL)
COR approved email update in lieu of phone call on Dec. 14. Copy of email and response is attached (Appendix A).

II. PROGRESS
A. Physical Exams
Physical exams have been performed weekly (Nov. 25, Dec. 3, Dec. 10, Dec. 17, and Dec. 23). All of the dogs’ physical exam findings have been within normal limits. The only exception is a presumptive histiocytoma unrelated to that is regressing spontaneously.

B. Vaccination
The second round of Info was administered Dec. 17. There were without incident with one important exception. The 4 animals in the “blue” group all vocalized in pain upon administration of This did not happen during the first round in November, nor did this happen with any other group. Upon physical exam on Dec. 23, all animals were bright, alert, and responsive.

Obtained via FOIA by White Coat Waste Project
Hi Andy,

Excellent, thank you for the update on the progress of this study.

Best,

Julio

---

From: Andy Moorhead <amoorhead@uga.edu>
Date: Tuesday, December 15, 2020 at 12:01 PM
To: Julio Aliberti <julio.aliberti@nih.gov>, Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>

Subject: HHSN272201700035I_75N93020F00003_December email update in lieu of conference call

Hello Julio,

Here is a summary of our progress to date:

1. Dogs arrived at UGA on Nov. 12. The study started on Nov. 18 after the 7-day mandated acclimation period. Physical exams were performed, CBC/chemistry was performed, urine collected, and serum and blood was shipped to the subcontractor. Proprietary Animals were prepared and administered according to instructions provided by the Proprietary. Animals were allocated in a random-block design.

2. Physical exams have been performed weekly (Nov. 25, Dec. 3, Dec. 10). On Dec. 17th, serum and whole blood will be collected, physical exams will be performed and the second round of Proprietary exams will be administered.

Please let me know what questions you have.

Thanks and have a good week,

Andy

---

Andrew R. Moorhead, DVM, MS, Ph.D. DACVM (Parasitology)
Assistant Professor
Director and PI
Francisca Research Resources Resource Center
Department of Infectious Diseases
University of Georgia
College of Veterinary Medicine
501 D. W. Brooks Drive
Athens, GA 30602
amoorhead@uga.edu
(706) 542-8168

Pronouns: he/him/his
Contract Number: HHSN272201700035I

Task Order Number: 75N93020F00003

Task: C12

Title: Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

Period of performance: December 25, 2020 to January 25, 2021

Contractor: University of Georgia
College of Veterinary Medicine
Department of Infectious Diseases
501 D.W. Brooks Drive
Athens, GA 30602

Due Date: January 25, 2021
The following is the report for the month of December with the reporting period ending January 25, 2020.

Progress for this month is documented in a progress email with the COR, Dr. Julio Aliberti, and under the heading PROGRESS.

I. UPDATE EMAIL (IN LIEU OF CONFERENCE CALL)
   COR approved email update in lieu of phone call on January 15, 2021. Copy of email and response is attached (Appendix A).

II. PROGRESS
   A. Physical Exams
      Physical exams have been performed weekly. All of the dogs' physical exam findings have been within normal limits.

   B. Proprietary Info
      The third round of Proprietary Info was administered January 14, 2021. They were without incident with one important exception. The 2 of 4 animals in the “blue” group all vocalized in pain upon administration of Proprietary Info.
      Upon physical exam on January 21, 2021, all animals were bright, alert, and responsive.
Hello Julio,

Here is a summary of our progress to date:

1. Dogs arrived at UGA on Nov. 12. The study started on Nov. 19 after the 7-day mandated acclimation period. Physical exams were performed, CBC/chemistry was performed, urine collected, and serum and blood was shipped to (subcontractor). (Proprietary Info) was prepared and administered according to instructions provided by the producer. Animals were allocated in a random-block design.

2. Physical exams have been performed weekly (Nov. 25, Dec. 3, Dec. 10). On Dec. 17th, serum and whole blood was collected, physical exams performed and the second (Proprietary Info) was administered.

3. On January 14, serum and whole blood was collected, physical exams performed and the third (Proprietary Info) was administered. Two of four dogs in the blue group vocalized in a pain response after administration (Proprietary Info).

Please let me know what questions you have.

Thanks and have a good week.

Andy

Andrew R. Moorhead, DVM, MS, Ph.D. DACVM (Parasitology)
Assistant Professor
Director and PI
Filarial Research Reagent Resource Center
Department of Infectious Diseases
University of Georgia
College of Veterinary Medicine
501 D. W. Brooks Drive
Athens, GA 30602
amoorhed@uga.edu
(706)-542-8168
Pronouns: he/him/his

Aliberti, Julio (NIH/NIAID) [E] <julio.aliberti@nih.gov>
Fri, Jan 15, 2021 at 10:31 AM
To: Andy Moorhead <amoorhed@uga.edu>
Cc: Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>

It seems like the blue group has shown consistent pain response. Any other sign?

Thanks,
Andy Moorhead <amoorhed@uga.edu>  
To: "Aliberti, Julio (NIH/NIAID) [E]" <julio.aliberti@nih.gov>  
Cc: Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>  
Subcontractor Info

No, those were the only ones.

Andy

[Quoted text hidden]

Aliberti, Julio (NIH/NIAID) [E] <julio.aliberti@nih.gov>  
To: Andy Moorhead <amoorhed@uga.edu>  
Cc: Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>  
Subcontractor Info

Ok, thanks.

[Quoted text hidden]
MEMORANDUM TO FILE

DATE: September 30, 2020

FROM: John Outen
Contracting Officer, OA, DEA, NIAID

TO: FILE

SUBJECT: Contract No. HHSN272201700035I
Task Order No. 75N93020F00003
University of Georgia

This memo to file is to document the following to the subject Contract file.

Date: 2020-5-14
To: Moorhead, Andrew
From: Office of Animal Care and Use

Initial Approval of Animal Use Protocol

Title: Protection of canines from proprietary info
AUP #: A2020 02-015-Y1-A0
Initial AUP Approval Date: 05-14-2020
Next AUP Annual Expiration Date: 05-14-2021
Terminal AUP Expiration Date: 05-14-2023

Funding Source: National Institutes of Health/other and various corporations
UGA's NIH Animal Welfare Assurance #: D16-00276/A3437-01

Information on the proposed contract action was not disseminated for publication in the Government-wide point of entry (i.e. FedBizzOpps) because of the exemption as prescribed by FAR 5.202(a)(6).

[Signature]
John Outen
Contracting Officer
Good morning Nicholas,

Please see attached for the Fully Executed Award of Task C12. The Contracting Officer is John Outen who is cc’d here.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contracting Officer
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)
Office of Acquisitions, DEA, NIAID, NIH-HHS
5601 Fishers Lane, Room 3D45, MSC 9821
Rockville, MD 20852-9821
Phone: 240-669-5344
Email: miranda.adams@nih.gov

From: Nicholas Alistair Hinson <nhinson@uga.edu>
Sent: Monday, September 14, 2020 3:10 PM
To: Adams, Miranda (NIH/NIAID) [E] <miranda.adams@nih.gov>
Cc: Andrew RIDDELL Moorhead <amoorhead@uga.edu>; Christian E Heindel <heindel@uga.edu>; Jenna L. Jones <jllester@uga.edu>; Aliberti, Julio (NIH/NIAID) [E] <julio.aliberti@nih.gov>; Bryan, Jonathan (NIH/NIAID) [E] <jonathan.bryan@nih.gov>
Subject: RE: HHSN272201700035I, Task C12, "Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs"

Thanks! Attached please find a partially executed copy of the agreement.
Sincerely,

Nicholas Hinson
Sponsored Projects Administration | Contract Manager

310 East Campus Rd | 308 Tucker Hall | Athens, GA 30602-1588
706-542-3650 | nhinson@uga.edu
Hi Nicholas,

Sorry about the typo. Please see attached for the corrected award.

This is a task order not a grant so there is no CFDA number.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contracting Officer
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)
Office of Acquisitions, DEA, NIAID, NIH-HHS
5601 Fishers Lane, Room 3D45, MSC 9821
Rockville, MD 20852-9821
Phone: 240-669-5344
Email: miranda.adams@nih.gov
Miranda,

Thank you, I'll review and get this signed. I do see one typo – the subaward in Section 4 references subcontractor info but it is actually with subcontractor info (as referenced in the table below). Would you like to revise and resend or is noting the typo via email sufficient?

Also could you confirm that there is no CFDA number for this project?

Thanks,

Nicholas Hinson
Sponsored Projects Administration | Contract Manager

310 East Campus Rd | 308 Tucker Hall | Athens, GA 30602-1588
706-542-3650 | nhinson@uga.edu

From: Adams, Miranda (NIH/NIAID) [E] <miranda.adams@nih.gov>
Sent: Monday, September 14, 2020 1:04 PM
To: Nicholas Alistair Hinson <nhinson@uga.edu>
Cc: Andrew RIDDLE Moorhead <amoorhed@uga.edu>; Christian E Heindel <heindel@uga.edu>; Jenna L. Jones <jlester@uga.edu>; Aliberti, Julio (NIH/NIAID) [E] <julio.aliberti@nih.gov>; Bryan, Jonathan (NIH/NIAID) [E] <jonathan.bryan@nih.gov>
Subject: HHSN2722017000351, Task C12, "Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs"

Good afternoon Nicholas,

Please see attached in reference to Task C12 award. Please have the authorized individual sign and return by COB, Tuesday, September 15th.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contracting Officer
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)