


**NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
TASK ORDER**

1. CONTRACT NO. HHSN272201700035I	2. TASK ORDER NO. 75N93020F00003	3. REQUISITION NO. 5824798	
4(A). TASK ORDER AWARD DATE See Block 13C	4(B). TASK ORDER EFFECTIVE DATE See Block 13(C)	4(C). TASK ORDER COMPLETION DATE January 15, 2022	
5(A). AWARD AUTHORITY <i>(Pursuant to FAR 16.505, 41 USC 253)</i> FAR 1.602-1; FAR 43.103(a)		5(B). TYPE OF ORDE [X] Cost Reimbursement [] Firm Fixed Price	
6. ISSUING OFFICE <i>(Address correspondence to)</i> National Institutes of Health, HHS National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 5601 Fishers Lane Rockville, MD 20852-9821		7. ADMINISTRATIVE OFFICE <i>(if different from block No. 6):</i>	
8. CONTRACTOR <i>(Name, address and ZIP code)</i> University of Georgia Research Foundation, Inc. 310 East Campus RD Tucker Hall Room 409 Athens, GA 30602-1589		9. CONTRACTING OFFICER'S REPRESENTATIVE <i>(Name, office code, and telephone number)</i> See Award Terms	
10(A). ACCOUNTING AND APPROPRIATION DATA FY 20 CAN 8470036 \$424,455			
10(B). FUNDING THIS ACTION \$424,455		10(C). TASK ORDER VALUE \$424,455	
11. DESCRIPTION OF SERVICES <i>(Scope of Work):</i> PURPOSE: To issue Task C12 for "Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs"			
12(A). NAME & TITLE OF SIGNER <i>(Typed)</i> Nicholas Hinson - Contract Manager		13(A). CONTRACTING OFFICER NAME <i>(Typed)</i> Miranda Adams OA, DEA, NIAID, NIH	
12(B). Signature 	12(C). DATE 9/14/2020	13(B). Signature	13(C). DATE 9/15/2020

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 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

Subcontractor Info for an amount not to exceed the following:

Subcontractor Info	Total Estimated Cost	
Base period	Estimated Costs	

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:

NAME	Role
Andrew Moorhead, DVM, MS, Ph.D., DACVM	Principal Investigator (PI)
Michael Dzimianski, DVM, MS	Co-Principal Investigator (Co-PI)

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 2.1 2.11, 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>).

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>

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/> . HHSAR Clauses at: <http://www.hhs.gov/policies/hhsar/subpart352.html> .

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

<u>FAR</u>	<u>DATE</u>	<u>TITLE</u>
<u>CLAUSE NO.</u>		
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over \$150,000)

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

<u>FAR</u>	<u>DATE</u>	<u>TITLE</u>
<u>CLAUSE NO.</u>		
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	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.
52.227-14	Dec 2007	Rights in Data - General, Alternate IV (Dec 2007)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Nov 2017	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property, Alternate II (April 2012)
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

<u>HHSAR</u>	<u>DATE</u>	<u>TITLE</u>
<u>CLAUSE NO.</u>		
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT W_ EDUCATIONAL INSTITUTION- Rev. 11/2017].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

No additional clauses beyond those of the base contract.

ARTICLE I.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:

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/> .

(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 I.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>) 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

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

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

Proprietary Info

Proprietary Info

SCOPE

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

evaluate the general safety of [Proprietary Info] in the dog model [Proprietary Info] [Proprietary Info]
[Proprietary Info]

REQUIREMENTS

Independently, 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 [Proprietary Info] 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 the [Proprietary Info] [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.
2. The Contractor shall acquire [Proprietary Info] [Proprietary Info]

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] [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]

The Contractor shall determine the [Proprietary Info] group against the control [Proprietary Info] group as indicated below:

1. Evaluation of whole blood for the presence [Proprietary Info]
2. Evaluation by *in vitro* [Proprietary Info] assay of the [Proprietary Info] [Proprietary Info]
3. Evaluation of [Proprietary Info] assay.

Subtask 5: Evaluation of [Proprietary Info]

The Contractor shall perform [Proprietary Info] assessments to determine the type of [Proprietary Info] responses elicited by [Proprietary Info]

1. Proprietary Info
2. 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 Proprietary Info
2. Collecting blood and urine and conducting blood and urine analysis (IDEXX, CBC, Urinalysis).



**PRE-CLINICAL MODELS OF INFECTIOUS DISEASES
ENCLOSURE 2 - REPORTING REQUIREMENTS
TASK C-12**

Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

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 Proprietary Info 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] 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.**

PRECLINICAL MODELS OF INFECTIOUS DISEASES

ENCLOSURE 3 - DELIVERY SCHEDULE

TASK C-12

Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs

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.

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

The above items shall be addressed and delivered to:

Addressee	Deliverable Item(s) No	Quantity and Form
Contracting Officer and Contracting Officer's Representative, NIAID	2, 3, 5, 6	1 electronic copy (pdf) submitted via eRDS
Contracting Officer's Representative, NIAID	1, 4	1 electronic copy (pdf) submitted via email

STUDY PROTOCOL

I. Objectives/Scope

The contractor shall evaluate the [Proprietary Info] in dogs, determine whether [Proprietary Info] samples from the [Proprietary Info] dogs can also [Proprietary Info] and evaluate the general safety [Proprietary Info] in the dog model of [Proprietary Info]

II. Approach

A. Overview: Dogs will be [Proprietary Info] in groups as outlined in Table 1. They will then be challenged on day 84 post-initial [Proprietary Info]. Animals will be euthanized after day 196 and [Proprietary 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 1: Animal Groups and [Proprietary Info] (Blinded [Proprietary Info] will be shipped as A, B, C, D)

First set of experiments:

Group	N	[Proprietary Info]	[Proprietary Info] (Day)	[Proprietary Info] subcutaneous (Day)
A	4	blinded	0, 28, 56	84
B	3	blinded	0, 28, 56	84
C	4	blinded	0, 28, 56	84
D	3	blinded	0, 28, 56	84

Second set of experiments:

Group	N	[Proprietary Info]	[Proprietary Info] (Day)	[Proprietary Info] subcutaneous (Day)
A	3	blinded	0, 28, 56	84
B	4	blinded	0, 28, 56	84
C	3	blinded	0, 28, 56	84
D	4	blinded	0, 28, 56	84

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

Proprietary Info

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

Table 3: Power Calculation

F tests – ANOVA: Fixed effects, omnibus, one-way		
Analysis:	Post hoc: Compute achieved power	
Input:	Effect size f	= 1.25
	α err prob	= 0.05
	Total sample size	= 14
	Number of groups	= 4
Output:	Noncentrality parameter λ	= 21.8750000
	Critical F	= 3.7082648
	Numerator df	= 3
	Denominator df	= 10
	Power (1- β err prob)	= 0.9087456

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 of [Proprietary Info] 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]

[Proprietary Info]

2. Test articles:

[Proprietary Info] obtained from the third party NIAID [Proprietary Info] 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:

Dogs will be [Proprietary Info] according to Tables 1 and 2.

1. Screening of dogs [Proprietary Info]

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 for [Proprietary Info] using a standard test kit per manufacturer's instructions. Also, dogs will be screened for [Proprietary Info]

[Proprietary Info] Dogs that are negative [Proprietary Info] and negative for [Proprietary Info]

[Proprietary Info] will be enrolled in the study. The screening will be performed in the PI's laboratory.

2. [Proprietary Info]

[Proprietary Info] will be prepared according to the [Proprietary Info] instructions [Proprietary Info] will be administered by intramuscular injection with a low dead-space syringe and 22-Ga 1 1/2" needle to maximize the amount of [Proprietary Info] injected.

3. Challenge [Proprietary Info]

[Proprietary Info] injected subcutaneously in amounts designated in Table 1 and on the schedule according to Table 2. Standard [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 [Proprietary Info] blood samples and serum isolated will be shipped to the subcontractor [Proprietary Info] [Proprietary Info]

Veterinarians and technical staff will collect urine by free catch or cystocentesis as designated on the schedule 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 [Proprietary Info] site

Results of Physical Exams and clinical observations will be recorded.

6. Shipping:

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

IV. Materials and Methods (Serum Analysis)

A. Evaluating the [Proprietary Info] responses:

[Proprietary Info]

B. Functional analysis of cells:

[Proprietary Info]

C. Evaluation of [Proprietary Info] responses:

[Proprietary Info]

Contract Number: HHSN272201700035I/75N93020F00003 Task: C09

October 2020

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 Proprietary 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/75N93020F00003 Task: C12 November 2020

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

-14 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/75N93020F00003 Task: C12 December 2020

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



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 **Proprietary Info** that is regressing spontaneously.

B. Vaccination

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





HHSN272201700035I_75N93020F00003_December email update in lieu of conference call

Aliberti, Julio (NIH/NIAD) [E] <julio.aliberti@nih.gov>

Tue, Dec 15, 2020 at 12:06 PM

To: Andy Moorhead <amoorhed@uga.edu>, Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>

Subcontractor Info

Hi Andy,

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

Best,

Julio

From: Andy Moorhead <amoorhed@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>

Subcontractor Info

Subcontractor Info

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. 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 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 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

Filariasis 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

Contract Number: HHSN272201700035I/75N93020F00003 Task: C12 January 2021

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 Proprietary Info was administered January 14, 2021 Proprietary Info 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.





Andy Moorhead [Personal Info]

HHSN272201700035I_75N93020F00003_January email update in lieu of conference call

4 messages

Andy Moorhead <amoorhed@uga.edu>

Fri, Jan 15, 2021 at 9:39 AM

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]

[Subcontractor Info]

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 Info] (subcontractor). [Proprietary Info] were prepared and administered according to instructions provided by the [Proprietary Info] 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

Filariasis 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>

[Subcontractor Info]

[Subcontractor Info]

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

Thanks,

Julio

[Quoted text hidden]

Andy Moorhead <amoorhed@uga.edu>

Fri, Jan 15, 2021 at 11:07 AM

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

Subcontractor Info

No, those were the only ones.

Andy

[Quoted text hidden]

Aliberti, Julio (NIH/NIAID) [E] <julio.aliberti@nih.gov>

Fri, Jan 15, 2021 at 11:11 AM

To: Andy Moorhead <amoorhed@uga.edu>

Cc: Elyssa Brooke Jacob <ejacob7@uga.edu>, Shana Skinner <Shanna.Skinner@uga.edu>

Subcontractor Info

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).



John Outen
Contracting Officer

From: [Adams, Miranda \(NIH/NIAID\) \[E\]](#)
To: [Nicholas Alistair Hinson](#)
Cc: [Andrew RIDDELL Moorhead](#); [Christian E Heindel](#); [Jenna L. Jones](#); [Aliberti, Julio \(NIH/NIAID\) \[E\]](#); [Bryan, Jonathan \(NIH/NIAID\) \[E\]](#); [Outen, John \(NIH/NIAID\) \[E\]](#); [Jackson, Charles \(NIH/NIAID\) \[E\]](#)
Subject: RE: HHSN272201700035I, Task C12, "Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs"
Date: Tuesday, September 15, 2020 10:13:00 AM
Attachments: [image001.png](#)
[image002.png](#)
[Task C12 Task Order Award - UGA FE.pdf](#)

Task Order attachment is pages 1-12 of this document.

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 <amoorhed@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

University of Georgia



From: Adams, Miranda (NIH/NIAID) [E] <miranda.adams@nih.gov>

Sent: Monday, September 14, 2020 2:59 PM

To: Nicholas Alistair Hinson <nhinson@uga.edu>

Cc: Andrew RIDDELL Moorhead <amoorhed@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"

[EXTERNAL SENDER - PROCEED CAUTIOUSLY]

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

From: Nicholas Alistair Hinson <nhinson@uga.edu>

Sent: Monday, September 14, 2020 2:45 PM

To: Adams, Miranda (NIH/NIAID) [E] <miranda.adams@nih.gov>

Cc: Andrew RIDDELL Moorhead <amoorhed@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"

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

University of Georgia



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 RIDDELL Moorhead <amoorhed@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: HHSN272201700035I, Task C12, "Lymphatic Filariasis Vaccine (LFguard) Efficacy Trial in Dogs"

[EXTERNAL SENDER - PROCEED CAUTIOUSLY]

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)

Office of Acquisitions, DEA, NIAID, NIH-HHS
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