SBIR Contract 75N93021C00044 Inimmune Corporation Phase II

Inimmune is proposing to use an established guinea pig model of allergic rhinitis to obtain proof of concept of INI-2004 efficacy in a second animal species. The reasons for considering the guinea pig model instead of the dog model are: allergic dog availability, time and costs.

Inimmune initially proposed to validate the use of INI-2004 for the treatment of allergic rhinitis in the ragweed allergic dogs Proprietary Info colony). The proposed dog studies were:

- 1B1: Efficacy study Proprietary Info
- 1B.2: Window of desensitization
- 1B.3: Proprietary Info INI-2004 administrations

Proprietary Info Inimmune contacted Proprietary Info where the dog studies were proposed, to schedule the dog studies described in this contract. Unfortunately, all the allergic dogs from the Proprietary Info colony have not been available Proprietary Info and the latest communications from Proprietary Info Proprietary Info indicated that no allergic dogs will be available Proprietary Info

Proprietary Info has instead proposed that Inimmune buys Proprietary Info old puppies that would be sensitized over an Proprietary Info and use the expected Proprietary sensitized dogs to evaluate INI-2004 Proprietary Info The cost for buying and sensitizing the dogs Proprietary Info Proprietary Info Thus testing Proprietary Info Proprietary Info INI-2004 in allergic dogs Proprietary Info would use Proprietary Info funds Proprietary Info

Dog studies budgeted in the SBIR contract using the allergic dog colony Proprietary Info
Dog ragweed study #1 - Efficacy study with Proprietary Info
Dog ragweed study # 2 – Window of desensitization: Proprietary Info
Dog ragweed study # 3 – Proprietary Info INI-2004 administrations: Proprietary Info
Current Proposal from Proprietary Info

Proprietary Info

Proprietary Info

Because of the unavailability of the allergic dogs Proprietary Info Proprietary Info Covid-related delays for obtaining and shipping supplies and workforce issues faced by

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CROs, Inimmune would like to use the established guinea pig model of allergic rhinitis/congestion (J Appl Physiol 125: 1563–1575, 2018) to generate proof of concept in a second animal species.

Guinea pigs have been used for many years in studies of allergic airway inflammation and are a more relevant model of human allergic rhinitis than mice. Guinea pigs can be sensitized to ragweed, our primary allergen indication, leading to allergic symptoms similar to human symptoms (sneezing, mucus secretion, runny nose). This model is highly relevant for our project and would be established by Inimmune personal using the University of Montana vivarium (fee usage) we previously used for our murine allergy studies. We have already discussed the possibility of doing guinea pig experiment with the UM vivarium manager.

The proposed studies are:

Study#1: training, assay development, INI-2004 dose finding Proprietary Info
Study#2: establish model of ragweed allergic rhinitis in GPs Proprietary Info
Study#3: INI-2004 treatment dose-optimization Proprietary Info
Study#4: desensitization window Proprietary Info
Study#5: therapeutic INI-2004 treatment Proprietary Info – or repeat of study#2 or 3 if issues establishing this animal model

Estimated timeline for completion: Proprietary Info

Estimated budget for these studies: Proprietary Info

Proprietary Info

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

SBIR Ph II Development Contract 75N93021C00044

January 20, 2022

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

1121 E Broadway, Suite 121, Missoula, MT

Obtained via FOIA by WCW Project

Contract Aims

- **Aim 1: Preclinical in vivo studies1A1: Formulation selection & optimization (mice)1A2: Confirm 7-day effectiveness (mice)1A3: Validation in Derp 1murine allergy model (mice)1B1: Efficacy study (dogs)1B.2: Window of desensitization (dogs)1B.3: Repeated INI-2004 administrations (dogs)**

Inimmune proposal:Do a POC study in the guinea pig (GP) model of congestion instead of dog studies (availability /delay…)?

J Appl Physiol 125: 1563–1575, 2018.

Proprietary Info

Proprietary Info

Proprietary Info

antibody data: IgG and IgE secondary antibodies available (also IgA if interested)Still digging for information on guinea pig IgG subtypes and if their functionalities are thought to be similar to humanVery basic flow cytometry (super limited guinea pig reagents, think CD45, CD4, CD8)

- We are designing a GP POC study and budgeting itBecause the GP model uses ragweed, a relevant allergen, can we do GP study only and not do 1A2 and 1A3 (ova model and Der p 1 murine experiments initially proposed?)

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Aim 1: Preclinical in vivo studies

Proposal for POC in guinea pigs

Proprietary Info

Study #1Training, assay development2004 dose finding

Study #2establish model of RWP allergic rhinitis in GPs as in Litvinov et al

Study #32004 treatment dose-finding

Study #4Schedule optimization

Proprietary Info

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

Aim 2: Formulation and stability studies

- 2A: Accelerated and long term stability Proprietary Info On-going in-house work – Paid by the SBIR Proprietary Info pment for stability indicating assay (required for GLP tox) Proprietary Info Proprietary Info Proprietary Info Proprietary Info - This method has been developed in-house with another API Proprietary Info

Work done at UNC Proprietary Info - Develop and evaluate the robustness of sample processing methods and LC-MS/MS assays Proprietary Info Proprietary Info (for release assay of drug product for GLP tox) - Proprietary Info Can this be charged to the SBIR?

Obtained via FOIA by WCW Project

Aim 3: Toxicology studies

- 3A: Mutagenicity Studies – Paid by Inimmune3B: Metabolism Studies Proprietary Info
  Paid by NIH3C: GLP multiple dose toxicity in rats, including pK/ADME– Paid by Inimmune

All contracts have been signed Analytical development starts in Proprietary Info rodent work and metabolism studies start in Proprietary Info

GLP multiple dose toxicity in rats requires GLP formulated drug product - INI-2004 manufacture: Proprietary Info scaled-up at Curia (NY); development lot Proprietary Info (Paid by Inimmune) - INI-2004 formulation: kick-off meeting with Curia (Glasgow) on Proprietary Info Proprietary Info development lot for GLP study Proprietary Info (Paid by Inimmune)

Obtained via FOIA by WCW Project

SBIR Ph II Development Contract 75N93021C00044

November 24, 2021

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

1121 E Broadway, Suite 121, Missoula, MT

Obtained via FOIA by WCW Project

Contract Aims

- Aim 1: Preclinical in vivo studies1A1: Formulation selection & optimization (mice) - COMPLETE1A2: Confirm 7-day effectiveness (mice)1A3: Validation in Derp 1murine allergy model (mice)1B1: Efficacy study (dogs)1B.2: Window of desensitization (dogs)1B.3: Repeated INI-2004 administrations (dogs)Aim 2: Formulation and stability studies2A: Accelerated and long term stability2B: Proprietary Info

Proprietary Info

Inimmune **On-going; 9 month stability**

Proprietary Info

WHITE COAT WATCH PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

Contract Aims

- **Aim 1: Preclinical in vivo studies – DOG STUDIES**

Challenges *Allergic dogs have been "booked" for the past* Proprietary Info Proprietary Info *: zoom meeting with* Proprietary Info *Small # of dogs may be available* Proprietary Info *(1 dose study) ORBuy* Proprietary *dogs to be sensitized* Proprietary Info *for our study – expect* Proprietary Info *dogs to be successfully sensitized* Proprietary Info *No allergic dogs available early next year..* Proprietary Info *Received quote for sensitizing ~ 6 mo old puppies and testing* Proprietary Info Proprietary Info

Proprietary Info

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS
Obtained via FOIA by WCW Project

Contract Aims

- **Aim 1: Preclinical in vivo studies1A1** Proprietary Info **(mice)1A2: Confirm 7-day effectiveness (mice)1A3: Validation in Derp 1murine allergy model (mice)1B1: Efficacy study (dogs)1B.2: Window of desensitization (dogs)1B.3: Repeated INI-2004 administrations (dogs)**

Inimmune proposal:Do a POC study in the guinea pig model of congestion instead of dog studies (availability /delay…)

J Appl Physiol 125: 1563–1575, 2018.

Proprietary Info

Proprietary Info

T cell cytokine data: guinea pig cytokine ELISA kits are readily available from Abclonal (they have everything)RWP or OVA antibody data: IgG and IgE secondary antibodies available (also IgA if interested)Still digging for information on guinea pig IgG subtypes and if their functionalities are thought to be similar to humanVery basic flow cytometry (super limited guinea pig reagents, think CD45, CD4, CD8)

- We are designing a GP POC study and budgeting itDoes NIH want first look at experimental design / budget before Inimmune start the GP studyBecause the GP model uses ragweed, a relevant allergen, can we do GP study only and not do 1A2 and 1A3 (ova model and Der p 1 murine experiments initially proposed?)

Obtained via FOIA by WCW Project

Contract Aims

- Aim 3: Toxicology studies3A: Mutagenicity Studies – Proprietary Info Ames test Proprietary Info – Proprietary Info Mammalian cell micronucleus test Proprietary Info In Vivo micronucleus test Proprietary Info Metabolism Studies Proprietary Info – Paid by NIHCYP450 induction and inhibition Proprietary Info Proprietary Info Membrane drug transporters Proprietary Info binding Proprietary Info Reaction phenotyping Proprietary Info 3C: GLP multiple dose toxicity in rats, including pK/ADME– Paid by Inimmune3C1: non-GLP pilot study Proprietary Info – N/A3C2: GLP pilot study Proprietary Info Proprietary Info (method validation/sample analysis/ Proprietary Info functional observation battery)

Proprietary Info

All contracts have been signed Analytical development Proprietary Info rodent work and metabolism studies Proprietary Info

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

Contract Aims

SBIR budget: Proprietary Info

Proprietary Info

- Proprietary Info ?The pre-IND enabling tox studies will require a CRO (Proprietary Info for GLP tox studies. Could we apply some of the unused NIH funds to pay for this cost (or other IND-enabling studies that will be done in the US?)

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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Inimmune

SBIR Ph II Development Contract 75N93021C00044

October 28, 2021

1121 E Broadway, Suite 121, Missoula, MT

Obtained via FOIA by WCW Project

Contract Aims

- Aim 1: Preclinical in vivo studies1A1: Formulation selection & optimization (mice)1A2: Confirm 7-day effectiveness (mice)1A3: Validation in Derp 1murine allergy model (mice)1B1: Efficacy study (dogs)1B.2: Window of desensitization (dogs)1B.3: Repeated INI-2004 administrations (dogs)Aim 2: Formulation and stability studies2A: Accelerated and long term

nimmune

Proprietary Info

Proprietary Info

STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS
WHITE COAT WCW PROJECT

Obtained via FOIA by WCW Project

Contract Aims

- Aim 3: Toxicology studies3A: Mutagenicity StudiesAmes testMammalian cell micronucleus testVivo micronucleus test3B: Metabolism StudiesCYP450 induction and inhibitionMembrane drug transportersPlasma protein bindingReaction phenotyping3C: GL dose toxicity in rats, including pK/ADME3C1: non-GLP pilot study3C2: GLP pilot study

Proprietary Info

Proprietary Info

Proprietary Info

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Contract Aims

- Aim 3: Toxicology studies3C: GLP Multiple dose toxicity in rats, including pK/ADMEnon-GLP Proprietary Info) and GLP Proprietary Info studies budgeted at (Proprietary Info

After consulting with Proprietary we will need to conduct the following studies for IND-enabling tox studies

Proprietary Info

Do we need approval from NIH to use Proprietary Info

- Contract work Proprietary Info dog studies):

Proprietary Info :Tox studies:

Budgeted Actual Price

Proprietary Info

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS
Obtained via FOIA by WCW Project

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE	OF	PAGES
	N/A	1		30

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75N93021C00044	09/01/2021	6128197

5. ISSUED BY CODE

National Institutes of Health
National Institutes of Allergy and Infectious Diseases
DEA, Office of Acquisitions
5601 Fishers Lane, Room: 3D10, MSC 9821
Rockville, Maryland 20852

6. ADMINISTERED BY *(If other than Item 5)* CODE

AIT-RCB

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

INIMMUNE CORP.
1121 E. Broadway, Suite 121
Missoula MT, 59802

CODE FACILITY CODE

8. DELIVERY

☐ FOB ORIGIN ☒ OTHER *(See below)*:
FOB Destination

9. DISCOUNT FOR PROMPT PAYMENT

N/A

10. SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN — ITEM: See Article G.3

11. SHIP TO/MARK FOR CODE N/A

See Article F.2

12. PAYMENT WILL BE MADE BY CODE N/A

See Article G.3

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 3304(a)( )

14. ACCOUNTING AND APPROPRIATION DATA

SBIR BioD CAN 8477185;
Funding Amount $1,836,453; SOCC 25.55

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Title:	Development of a new TLR4 agonist for the treatment of Allergic Rhinitis			FY 2021	$1,836,453.00
Period:	September 01, 2021 through August 31, 2023				
Contract Type:	Firm-Fixed Price				

15G. TOTAL AMOUNT OF CONTRACT ▶ $1,836,453.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return _1_ copy to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD *(Contractor is not required to sign this document.)*

Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or Print)*

Helene Bazin-Lee
VP Discovery

20A. NAME OF CONTRACTING OFFICER

Tom Bahrami
Contracting Officer, OA, NIAID, NIH, DHHS

19B. NAME OF CONTRACTOR Inimmune Corp

BY Personal Signature
(Signature of person authorized to sign)

19C. DATE SIGNED 08/26/2021

20B. UNITED STATES OF AMERICA

BY Som T. Bahrami -S
(Signature of Contracting Officer)

Digitally signed by Som T. Bahrami -S
Date: 2021.08.26 10:13:32 -04'00'

20C. DATE SIGNED

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

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STANDARD FORM 26 (REV. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

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WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The goal of this research program is to develop a self-administered intranasal TLR4 agonist to treat allergic rhinitis. Unlike antigen-specific therapy, this allergen independent approach is expected to be broadly applicable to a vast array of allergens patients are exposed to. Such treatment would provide relief within hours of administration, providing short-term symptom control, and has the potential to deliver long-term disease remission via allergen dependent T cell and B cell memory responses. The TLR4 agonist developed by Inimmune is superior in terms of potency and stability to other licensed TLR4 adjuvants. The first objective of this proposal is to complete pre-clinical in vivo studies to select the optimal formulation and administration schedule Proprietary Info Proprietary Info Proprietary Info

In the second objective, we will perform accelerated and long term stability studies of the optimal formulation and characterization test of the nasal spray device. The third objective includes non-GLP and GLP multiple dose toxicity Proprietary Info Proprietary Info The work proposed herein comprises the pre-clinical basis to advance our TLR4 agonist for the treatment of allergic rhinitis to the pre-IND stage.

ARTICLE B.2. PRICES

a. The total fixed price of this contract is $1,836,453.

b. Upon delivery and acceptance of the services described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Progress Report	Due Date	Price
Quarterly Progress Report	12/15/2021	Itemized Cost
Quarterly Progress Report	03/15/2022	
Quarterly Progress Report	06/15/2022	
Quarterly Progress Report	09/15/2022	
Quarterly Progress Report	12/15/2022	
Quarterly Progress Report	03/15/2023	
Quarterly Progress Report	06/15/2023	
Final Report	08/31/2023	
TOTAL FIRM FIXED PRICE		$1,836,453

ARTICLE B.3. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

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a. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

b. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. 75N93021C00044

c. **SBIR Funding Agreement Certification**

The SBIR Funding Agreement Certification form, located in SECTION J, must be completed at the time of award prior to the performance of work under this contract, in accordance with the SBIR Policy Directive issued by SBA (October 18, 2012).

For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards," located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-116.html .

Obtained via FOIA by WCW Project

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. 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 Description, dated 10/26/2020, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

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."

a. **Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. **Quarterly Progress Report**

a. This report shall include a summation of the monthly progress reports/a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b. A monthly report will not be submitted for the final month of the quarter.

c. The first report shall be due December 15, 2021. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

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Period of Performance	Due Date of Quarterly Report
09/01/2021- 11/31/2021	12/15/2021
12/01/2021-02/29/2022	03/15/2022
03/01/2022-05/31/2022	06/15/2022
06/01/2022-08/31/2022	09/15/2022
09/01/2022-11/31/2022	12/15/2022
12/01/2022-02/29/2023	03/15/2023
03/01/2023-05/31/2023	06/15/2023
06/01/2023-08/31/2023	08/31/2023 [see ' Final Report' section below.]

2. **Final Report**

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. A/An Quarterly report will not be required for the period when the Final Report is due.

Prior the submission of a Final Report, the Contractor shall provide the Contracting Officer with 1 copy of the draft Final Report prior to the expiration date of this contract. The Contracting Officer's Representative (COR) will review the draft report and provide the Contracting Officer with comments within 10 Calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

3. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

b. **Other Reports/Deliverables**

1. **NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification**

In accordance with the SBIR/STTR Reauthorization Act of 2011, the contractor shall complete and submit the NIH Small Business Innovation Research (SBIR) Life Cycle Certification form, located in SECTION J, of the contract to the Contracting Officer. This certification is required to ensure the contractor is meeting the program's requirements during the life cycle of the contract.

The Life Cycle Certification form shall be submitted as follows:

- Phase I SBIR Contractors shall submit the Certification at the time of receiving final payment or disbursement.
- Phase II SBIR Contractors shall submit the Certification prior to receiving more than 50% of the total contract amount **AND** prior to final payment or disbursement.

The Contracting Officer, may, at any time after ward request further clarifications and supporting documentation in order to assist in the verification of any information provided by the contractor.

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For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards, " located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-116.html.

REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE

All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, 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."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following website address: http://erds.niaid.nih.gov

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

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SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the COR designated in Article G.1. is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
5601 Fishers Lane
Bethesda, MD 20892-9830

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

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

FAR Clause **52.246-7, Inspection of Research and Development - Fixed Price** (August 1996).

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from 9/01/2021 through 08/31/2023.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Description Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Description	Quantity	Delivery Schedule
(1)	Quarterly Progress Reports	1 electronic copy	Due on or before the dates listed in Article C.2.
(2)	Final Report and Summary of Salient Results	1 electronic copy	Due on or before the dates listed in Article C.2.
(3)	NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification	1 electronic copy	Due on or before the dates listed in Article C.2.
(4)	Final Invention Statement – See Article C.3.	1 electronic copy	Due on or before the dates listed in Article C.2.

b. The above items shall be addressed and delivered to:
All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via **eRDS (NIAID's electronic Report Deliverable Submission), available at the following website: https://erds.niaid.nih.gov.**

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.

52.242-17, Government Delay of Work (April 1984).

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SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

Michael Minnicozzi, Ph.D.
Contracting Officer's Representative (COR)
Division of Allergy, Immunology, and Transplantation
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, Rm 6B59
Bethesda, MD 20892-9828
Phone: 240.627.3532
Email: Redacted by agreement

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 contract; and (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. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

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 thirty 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.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
Personnel	

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ARTICLE G.3. INVOICE SUBMISSION

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. The Contractor shall submit invoice to the National Institutes of Health (NIH)/Office of Financial Management (OFM) via email at invoicing@nih.gov with a copy to the approving official, as directed below. The Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice shall be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

   The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer's Representative:

   Approving Official: Contracting Officer

   Name- Maribel Miranda Email Address- Redacted by agreement

   Contracting Officer's Representative

   Name- Michael Minnicozzi, PhD Email Address- Redacted by agreement

   For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@incontactemail.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

   Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases .

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned*

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to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.

d. Invoice Matching Option. This contract requires a two-way match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is:

SBIR Topic 091 Phase II: Development of a new TLR4 agonist for the treatment of Allergic Rhinitis

g. Contract Line Items as follows:

Line Item #	Line Item Description	Period of Performance	Funded Amount
1	Base Period	09/01/2021-08/31/2023	$1,836,453

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared based on a schedule to be determined by the Contracting Officer.

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Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

http://www.cpars.gov

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) available at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines*.

The *NIH Guidelines* stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the *NIH Guidelines* as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the *NIH Guidelines*. Further information about compliance with the *NIH Guidelines* can be found on the NIH Office of Science Policy website available at: http://osp.od.nih.gov/.

ARTICLE H.3. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

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ARTICLE H.4. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.7. 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 Sates 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.

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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).

(End of clause)

ARTICLE H.8. 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, as modified in the Final Proposal Revision (FPR), dated May 19, 2021, which is incorporated by reference.

ARTICLE H.9. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIAID environment (NIH) directly, or through collaborative research or holding facilities under contract to NIAID except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NIAID environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.10. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.11. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.12. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum of two-thirds of the research and/or analytical effort [total labor hours/total contract costs less profit/fee] conducted under this contract. Any deviation from this requirement must be approved in writing by the Contracting Officer.

ARTICLE H.13. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed,

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acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

b. The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

c. The Section 508 accessibility standards applicable to this contract are: (Contract staff must list applicable standards)

d. In the event of a modification(s) to this contract or order,which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

ARTICLE H.14. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015)

a. a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of

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the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and standards/communications-and-it/about-the-section-508-standards .

c. c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

- The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

ARTICLE H.15. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93021C00044"

a. **Advanced Copies of Press Releases**

Obtained via FOIA by WCW Project

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.16. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: https://oig.hhs.gov/fraud/report-fraud/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.17. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.18. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://apps.usfa.fema.gov/hotel/.

ARTICLE H.19. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

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PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT

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:

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Jun 2020*	*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	*Jun 2020*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*Jun 2020*	*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	*Jun 2020*	*Limitation on Payments to Influence Certain Federal Transactions (Over the Simplified Acquisition Threshold)*
52.203-17	*Jun 2020*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-19	*Jan 2017*	*Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*Jun 2020*	*Reporting Executive Compensation and First-Tier Subcontract Awards*
52.204-13	*Oct 2018*	*System for Award Management Maintenance*
52.204-25	*Aug 2020*	*Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*
52.209-6	*Jun 2020*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment*
52.215-2	*Jun 2020*	*Audit and Records - Negotiation*
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	*Aug 2020*	*Subcontractor Certified Cost or Pricing Data*
52.215-14	*Jun 2020*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*

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FAR CLAUSE NO.	DATE	TITLE
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	Jun 2020	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.219-6	Nov 2020	Notice of Total Small Business Set-Aside
52.219-8	Aug 2018	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-14	Mar 2020	Limitations on Subcontracting
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	Jun 2020	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
52.222-37	Jun 2020	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	Oct 2020	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Jun 2020	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	Jan 2021	Buy American - Supplies
52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Jun 2020	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.
52.227-20	May 2014	Rights in Data - SBIR Program
52.229-3	Feb 2013	Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)
52.229-4	Feb 2013	Federal, State, and Local Taxes (State and Local Adjustments) (Over the Simplified Acquisition Threshold)
52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment
52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations

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FAR CLAUSE NO.	DATE	TITLE
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-1	Aug 1987	Changes - Fixed Price, Alternate V (Apr 1984)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Jun 2020	Subcontracts for Commercial Items
52.246-25	Feb 1997	Limitation of Liability - Services (Over the Simplified Acquisition Threshold)
52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
52.249-9	Apr 1984	Default (Fixed-Price Research and Development)(Over the Simplified Acquisition Threshold)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
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
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT- Rev. 03/2021].

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ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (January 2017)

b. FAR Clause **52.249-4, Termination for Convenience of the Government (Services) (Short Form)** (April 1984), is deleted in its entirety and FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed Price)** (April 2012) is substituted therefor.

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

ARTICLE I.3. Additional 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.

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

1. FAR Clause **52.204-14**, **Service Contract Reporting Requirements** (October 2016).
2. FAR Clause **52.204-24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment** (December 2019).
3. FAR Clause **52.204-25, Prohibition on Contracting for Certain Telecommunications** (August 2019).
4. FAR Clause **52.204-26 Covered Telecommunications Equipment or Services-Representation** (October 2020).
5. FAR Clause **52.209-10, Prohibition on Contracting with Inverted Domestic Corporations** (November 2015).
6. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).
7. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (November 2020).
8. FAR Clause **52.227-14, Rights in Data - General** (May 2014).
9. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
10. FAR Clause **52.244-5, Competition in Subcontracting** (December 1996).

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

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.*)

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ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

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

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (June 2016)

a. *Definitions* . As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

b. Safeguarding requirements and procedures.

1. The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

i. Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

ii. Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

iii. Verify and control/limit connections to and use of external information systems.

iv. Control information posted or processed on publicly accessible information systems.

v. Identify information system users, processes acting on behalf of users, or devices.

vi. Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

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ix. Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

x. Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

xi. Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

xii. Identify, report, and correct information and information system flaws in a timely manner.

xiii. Provide protection from malicious code at appropriate locations within organizational information systems.

xiv. Update malicious code protection mechanisms when new releases are available.

xv. Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. *Other requirements.* This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

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PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated 10/26/2020, 5 pages.

2. Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2

Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2, (3/21), 3 pages.

3. Electronic Invoicing Instructions for NIH Contractors/Vendors

Electronic Invoicing Instructions, 2 pages.

4. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (12/15), 2 pages.

5. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, 2 pages.

6. eRDS Electronic to Report Deliverable

eRDS Electronic to Report Deliverable, Submission User Guide, 8 pages.

7. Commitment To Protect Non-Public Information

Commitment To Protect Non-Public Information, 1 page. Located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf

8. Employee Separation Checklist

Employee Separation Checklist, 1 page. Fillable PDF format located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf

9. NIH Small Business Innovation Research (SBIR) Program Funding Agreement Certification

NIH Small Business Innovative Research (SBIR) Program Funding Agreement Certification, 3 pages, located at: https://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Funding%20Agreement%20Certification.pdf

10. NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification

NIH Small Business Innovative Research (SBIR) Program Life Cycle Certification, 3 pages, located at: http://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Life%20Cycle%20Certification.pdf.

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PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

   (End of clause)

2. NIH Representations & Certifications

   Certification for: INIMMUNE CORP DUNS: 080350279
   Certification Validity From: Mon May 10 13:46:13 EDT 2021
   Certification Validity To: Tue May 10 13:46:13 EDT 2022

3. Animal Welfare Assurance Number

Proprietary Info

END of the SCHEDULE

(CONTRACT)

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

Obtained via FOIA by WCW Project

Attachment 1
Statement of Work

WHITE COAT WASTE PROJECT

Obtained via FOIA by WCW Project

Appendix E

STATEMENT OF WORK

TITLE: Development of a new TLR4 agonist for the treatment of allergic rhinitis.

I. Background Information

Provide a general, brief summary of what needs the research on this contract will be addressing. Information from the Topic description may be useful to include for context.

The goal of this program is to accelerate the pre-clinical development of a single immunomodulator, a novel TLR4 agonist, for the treatment of allergic rhinitis.

Allergic rhinitis (AR) affects over 500 million people worldwide and carries a significant health and economic burden. The incidence and prevalence of AR have continued to rise rapidly in recent years and AR is estimated to affect 10 to 30% of the world population including up to 40% children, who bear the greatest burden of allergic diseases. Current therapeutic options are avoidance of allergens, symptomatic medication, and allergen specific immunotherapy (AIT). Although symptomatic medications are effective in treating the symptoms of AR and are generally well tolerated with few side effects, they do not alter the underlying disease and do not prevent disease progression. AIT is the only treatment modality that has been shown to alter the underlying immunologic mechanisms that cause AR and allergic asthma, with benefits that may last for several years after treatment discontinuation. Several drawbacks of AIT include the treatment duration, cost, potential severe side effects and low patient adherence, thus requiring the development of alternative safe and effective approaches for the treatment of AR. The objective of this SBIR Phase II development proposal is to advance our TLR4 agonist for the treatment of allergic rhinitis to the pre-IND stage. The ultimate goal of this research project is the development of an Proprietary Info stand-alone TLR4 agonist that will provide relief against AR symptoms within hours of administration. In addition to providing short-term symptom control, this approach also has the potential to deliver long-term disease remission. Unlike AIT, this non allergen-specific approach is expected to provide protection against a wide variety of environmental allergens.

II. Scope

Provide a one to two sentence statement of what is expected to be accomplished under the contract.

Under this contract, we will perform extended pre-clinical IND-enabling studies including additional murine efficacy studies and validate our immunomodulator in an established canine model of AR, formulation stability studies and toxicology testing.

III. Objectives

State the specific objectives and anticipated end results of the proposed Phase II effort

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The specific goal of this SBIR Phase II development proposal is to advance our lead TLR4 agonist INI-2004 towards pre-IND by

(i) completing in-house murine preclinical efficacy studies (Task 1A) and validate our candidate in the established canine model of allergic rhinitis (Task 2B) to select an optimal formulation and an administration schedule;

(ii) perform accelerated and long term stability study of the optimal formulation (Task 2A) and characterization test Proprietary Info (Task 2B); and

(iii) complete toxicology studies including mutagenicity testing (Task 3A), metabolism studies (Task 3B), non-GLP (Task 3C.1) and a GLP multiple dose toxicity in rats (Task 3C.2) to assess the safety of repeated administration of our TR4 agonist.

At the end of this phase II, we are anticipating obtaining the preclinical data to support the weekly Proprietary Info administration of the lead formulation of INI-2004 Proprietary Info Proprietary Info and safety data in a rodent specie. These preclinical studies will form the basis of our pre-IND document.

IV. Services to be Performed.

Begin this section with the following language: "The contractor shall independently perform all work and furnish all labor, materials, supplies, equipment, and services (except as otherwise specified in the contract) to perform the following services:"

The contractor shall independently perform all work and furnish all labor, materials, supplies, equipment, and services (except as otherwise specified in the contract) to perform the following services.

A. Specific Requirements – List all tasks in a logical sequence, in an outline format, to precisely describe what is expected of the contractor in performance of the work. Tasks should contain enough detail to establish parameters for the project and keep the effort focused on meeting the objectives.
Do not include any proprietary information.

Specifically, the Contractor shall:

1. Independently perform all work and furnish all labor, materials, supplies, equipment, and services to complete the preclinical in vivo studies including the selection of an optimal INI-2004 formulation and administration schedule in mice using an established OVA murine model and the clinically relevant Der p 1 antigen (Inimmune), and validating this formulation/administration schedule in the well-established canine model of allergic rhinitis Proprietary Info

    a. Subactivity: the Contractor will evaluate Proprietary Info formulations of INI-2004 and compare them to Proprietary Info formulation in our established murine OVA allergy model (Inimmune).

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b. Subactivity: the Contractor will confirm the Proprietary Info effectiveness of the optimal formulation of INI-2004 in our established murine OVA allergy model (Inimmune).

c. Subactivity: the Contractor will validate the optimal formulation and Proprietary Info administration effectiveness of INI-2004 in the murine Der p 1 allergy model (Inimmune).

d. Subactivity: the Contractor will perform an efficacy study in an established model of canine allergic rhinitis by evaluating Proprietary Info INI-2004 in ragweed-sensitized dogs Proprietary Info

e. Subactivity: the Contractor will investigate the window of desensitization provided by a single administration of INI-2004 in ragweed-sensitized dogs Proprietary Info Proprietary Info

f. Subactivity: the Contractor will investigate the safety and efficacy of Proprietary Info Proprietary Info of INI-2004 in ragweed-sensitized dogs Proprietary Info Proprietary Info

2. Independently perform all work and furnish all labor, materials, supplies, equipment, and services to perform the formulation and stability studies (Inimmune, Proprietary Info Proprietary Info

a. Subactivity: the Contractor will prepare and characterize Proprietary Info Proprietary Info formulations of INI-2004 for murine and canine studies and perform accelerated and long-term stability studies on these formulations (Inimmune).

b. Subactivity: the Contractor will evaluate Proprietary Info Proprietary Info dog ragweed studies and in subsequent clinical trials (Inimmune, Proprietary Info

3. Independently perform all work and furnish all labor, materials, supplies, equipment, and services to perform toxicology studies (Covance and Proprietary Info

a. Subactivity: the Contractor will perform mutagenicity testing of INI-2004 (Covance).

b. Subactivity: the Contractor will perform metabolism studies of INI-2004 (Covance).

c. Subactivity: the Contractor will evaluate the safety of Proprietary Info administrations (3 doses) of INI-2004 in the lead formulation in a pilot toxicity study in rats Proprietary Info

b. Subactivity: the Contractor will evaluate the safety of Proprietary Info administrations (3 doses) of INI-2004 in the lead formulation in a GLP toxicity study in rats Proprietary Info

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B. If the research plan includes the use of human subjects or animals, briefly describe the parameters of this use. Refer to Sections 4 and 8 of the Solicitation for further guidance.

The contractor's research plan includes the use of mice and dogs to validate the formulation and administration schedule of the TLR4 agonist, and rats to evaluate the safety of Proprietary Info administrations of the TLR4 agonist. The murine allergy studies will take place at the University of Montana (Missoula, MT) vivarium under an external contract agreement between Inimmune and UM. The University of Montana vivarium is equipped with state-of-the art equipment including micro-isolator cages and large holding and procedural rooms required for animal husbandry. The University of Montana has an approved Assurance on file with the Office of Laboratory Animal Welfare (OLAW) and AAALAC accreditation. Murine allergy studies will take place under the University of Montana IACUC approved animal use protocol (AUP) 002-19. Prior to any of proposed work taking place that does not fall under the experiments allowed by this AUP will require a new AUP to be reviewed and approved by the University of Montana IACUC before those experiments take place. Please see the Vertebrate Animals section of the Detailed Approach and Methodology for further details. The dog studies will be performed by Proprietary Info and the rat studies will be performed by Proprietary Info

The contractor shall independently perform all work and furnish all labor, materials, supplies, equipment, and services to complete animal studies in full compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The offeror (through the University of Montana) shall maintain a written Animal Welfare Assurance (Assurance) on file with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). Prior to starting any work involving animals, the Contractor shall provide the Contracting Officer verification of IACUC approval for all work performed as part of this contract.

C. Reports & Deliverables - Describe end products and deliverables, and describe periodic/final reports required to monitor work progress under the contract.

The end product of this SBIR development will be the completion of the following pre-IND-enabling studies:

(i) selection of an optimal formulation for Proprietary Info administration of a TLR4 agonist to treat allergic rhinitis

(ii) selection of an administration schedule of the TLR4 agonist after preclinical studies in the established canine model of allergy rhinitis

(iii) 1-year stability studies of formulated INI-2004, Proprietary Info Proprietary Info

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(iv) toxicity studies including mutagenicity and metabolism studies and one GLP multiple dose toxicity in rats

Deliverables will exist in the form of 4 milestones that will be met throughout the course of this SBIR:

Milestone 1: Complete preclinical murine studies by Proprietary Info

Milestone 2: Complete preclinical canine studies by Proprietary Info

Milestone 3: Complete formulation and stability studies by Proprietary Info

Milestone 4: Complete preclinical toxicology studies by Proprietary Info

We will complete semi-annual and annual technical and financial reports to monitor work progress under this SBIR.

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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Attachment 2
Invoice Instructions

WHITE COAT WASTE PROJECT

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INVOICE INSTRUCTIONS FOR NIH FIXED-PRICE CONTRACTS, NIH(RC)-2

Format: Submit payment requests on Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, or the Contractor's self-generated form provided it contains all of the information prescribed herein. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Submit payment requests upon delivery and acceptance of goods or services unless otherwise authorized by the Contracting Officer.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Preparation and Itemization of the Payment Request: Prepare payment requests as follows:

Note: All information must be legible or the invoice will be considered improper and returned to the Contractor.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Acquisition Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Voucher Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a Contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order.

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Payment requests with duplicate invoice numbers will be considered improper and returned to the Contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the Contractor chooses to reclaim those costs on a supplemental invoice, the Contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(d) **Date Invoice/Voucher Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (as applicable).

(f) **Contract Title:** Insert the contract title listed on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Fixed-Price of Contract/Order:** Insert the total fixed-price of the contract/order.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Identify the Central Point of Distribution, as specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Description of Supplies or Services:** Provide a description of the supplies or services, by line item (if applicable), quantity, unit price (where appropriate), and total amount. The item description, unit of measure, and unit price **must match** those specified in the contract. For example, if the contract specifies 1 box of hypodermic needles (100/box) with a unit price of $50.00, then the invoice must state 1 box, hypodermic needles (100/box), $50.00, **not** 100 syringes at $0.50 each. Invoices that do not match the line item pricing in the contract will be considered improper and will be returned to the Contractor.

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(n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period, including any adjustments, if applicable. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request.

(o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed to date, including any adjustments as applicable. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request.

(p) **Freight or Delivery Charges:** Identify all charges for freight or express shipments, other than f.o.b. destination, as a separate line item on the invoice. (If shipped by freight or express, and charges are more than $25, attach prepaid bill.)

(q) **Government Property:** If the contract authorizes the purchase of any item of Government Property (e.g., equipment), the invoice must list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- Contracting Officer Authorization (COA) Number, if the equipment is not covered by the Property Schedule.

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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Attachment 3
Electronic Invoicing Instructions

WHITE COAT WASTE PROJECT

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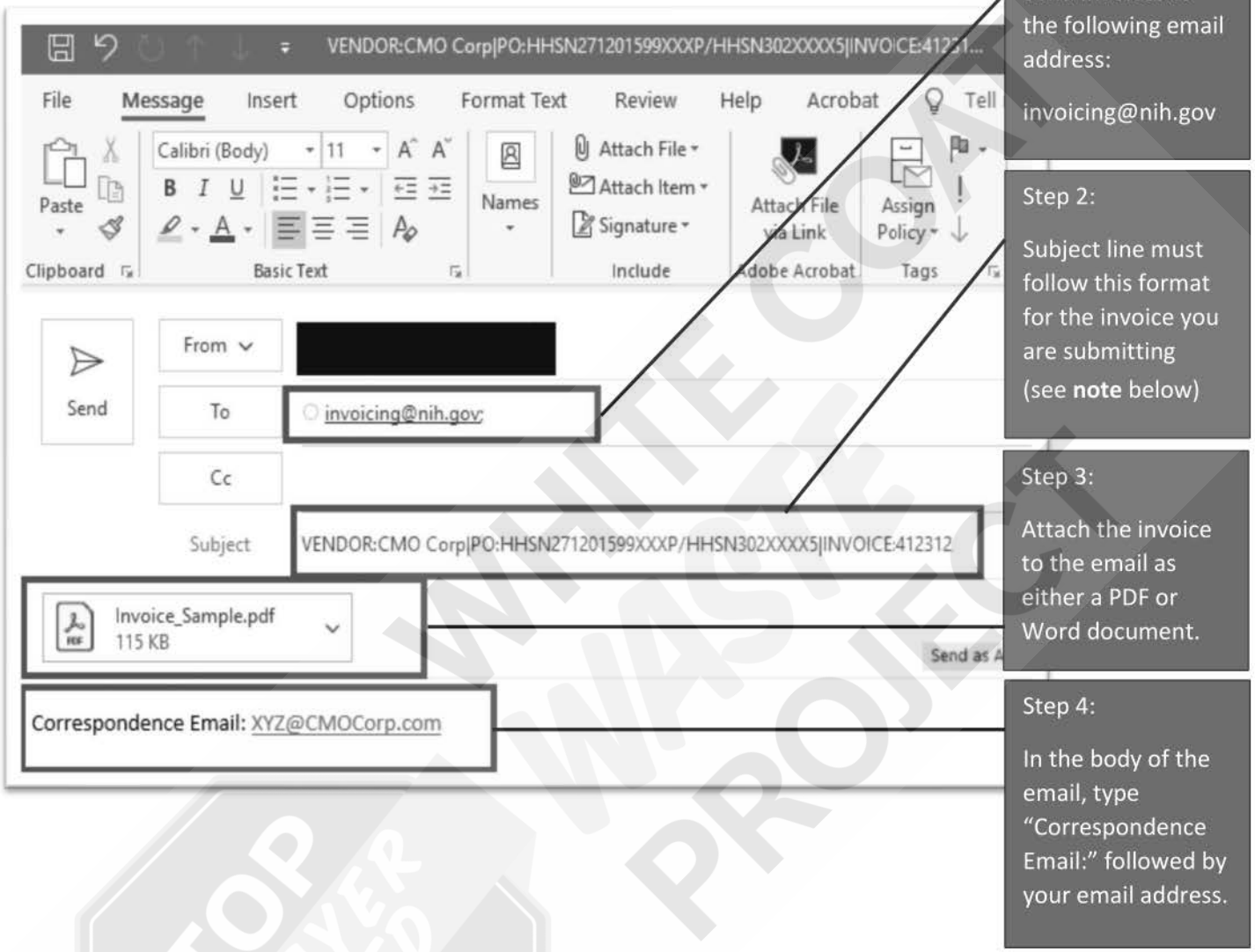
Instructions for Submitting Electronic Invoices via Email to the NIH Office of Financial Management (OFM) Effective April 23, 2020

4 Steps to Create the Invoice Submission Email



Step 2 Note: The key words (**Vendor**, **PO**, and **Invoice**), Colon (**:**) character following the keywords and the **PIPE** (**|**) character must be present to identify the information. The pipe (**|**) character is entered by pressing and holding the shift key and the backslash (****) key at the same time.

EXAMPLE: Vendor: name of the contractor or vendor**|PO:** Contract Number/Release Number**|Invoice:**9999999

For your reference, below is a chart listing examples of the correct and incorrect subject lines. Note: These are just examples, you must enter the applicable information for the invoice you are submitting.

Subject Line	Correct	Incorrect
Vendor: XYZ Corp|PO: Contract Number/Release Number|Invoice:XYASAD	✓	
XYZ Corp|PO # Contract Number\Release Number|Invoice # XYASAD		✗
XYZ Corp|Purchase Order # Contract Number\Release Number|Invoice # XYASAD		✗
XYZ Corp| Contract Number\Release Number| XYASAD		✗
Vendor: XYZ Corp,PO: Contract Number\Release Number,Invoice:XYASAD		✗

Obtained via FOIA by WCW Project

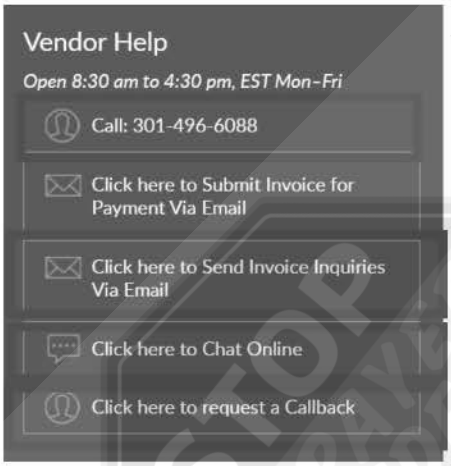
Instructions for Submitting Electronic Invoices via Email to the NIH Office of Financial Management (OFM) Effective April 23, 2020

Reminders:

- Must submit only **one** invoice per email.
- Follow the system size limits that apply to the email and each invoice: individual email attachments cannot exceed 5 megabytes each; and the email plus all attachments cannot exceed a total of 30 megabytes.
- Clearly identify a valid and complete contract number on each invoice
- Clearly identify a valid and complete order number on each invoice
- Clearly identify an accurate DUNS number on each invoice
- DO NOT include confidential information such as Social Security Numbers (do not include TIN if it is a Social Security Number)
- The invoice attached to the email must be in a PDF or Word format

The date/time that a valid invoice is submitted electronically to the email box (invoicing@nih.gov) will be the same date/time logged as the invoice is received by NIH.

Please do not hand-deliver invoices to any NIH office. Please follow the above electronic submission instructions until further notice. In addition, please note that your contract or order will not be modified to reflect the above changes to the invoicing instructions. Failure to follow the above electronic submission instructions may result in invoice processing delays.



Questions? Please direct inquiries regarding the status of invoices such as receipt of invoices, due date, or payment of invoices to the OFM Commercial Accounts Branch, Customer Service Office. The OFM Customer Service contact information and methods to contact are available at OFM website: https://ofm.od.nih.gov/Pages/Customer-Service.aspx

The Customer Service Office is open Monday – Friday from 8:30 am to 4:30 pm (Eastern Standard Time) and is closed daily between 12:00 pm to 1:00 pm (Eastern Standard Time).

Instructions for Contractor Courtesy Copy Electronic Invoice Submission to the Contracting Officer (CO):

The Contractor shall send the OFM-submitted invoice to the NIH Contracting Officer.

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Attachment 4
Safety and Health

WHITE COAT WASTE PROJECT

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Safety and Health, HHSAR 352.223-70 (DEC 2015)

a. To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.
    1. In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:
        I. 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at https://www.osha.gov/.
        II. Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

    2. The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:
        I. Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at http://www.cdc.gov/biosafety/publications/index.htm.
        II. Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals.

b. Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable ``Changes'' clause set forth in this contract.

c. The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to

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toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

d. If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

e. The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

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Attachment 5
Disclosure of Lobbying Activities, SF-LLL

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DISCLOSURE OF LOBBYING ACTIVITIES

OMB Control Number: 4040-0013
Expiration Date: 2/28/2022

Complete this form to disclose lobbying activities pursuant to 31 U.S.C.1352

1. * Type of Federal Action:	2. * Status of Federal Action:	3. * Report Type:
☒ a. contract	☐ a. bid/offer/application	☒ a. initial filing
☐ b. grant	☒ b. initial award	☐ b. material change
☐ c. cooperative agreement	☐ c. post-award	
☐ d. loan		
☐ e. loan guarantee		
☐ f. loan insurance		

4. Name and Address of Reporting Entity:

☒ Prime ☐ SubAwardee

** Name*

** Street 1* *Street 2*

** City* *State* *Zip*

Congressional District, if known:

5. If Reporting Entity in No.4 is Subawardee, Enter Name and Address of Prime:

6. * Federal Department/Agency:

7. * Federal Program Name/Description:

CFDA Number, *if applicable:*

8. Federal Action Number, *if known:*

9. Award Amount, *if known:*

$

10. a. Name and Address of Lobbying Registrant:

Prefix ** First Name* *Middle Name*

** Last Name* *Suffix*

** Street 1* *Street 2*

** City* *State* *Zip*

b. Individual Performing Services (including address if different from No. 10a)

Prefix ** First Name* *Middle Name*

** Last Name* *Suffix*

** Street 1* *Street 2*

** City* *State* *Zip*

11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when the transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

*** Signature:**

***Name:** *Prefix* ** First Name* *Middle Name*

** Last Name* *Suffix*

Title: **Telephone No.:** **Date:**

Federal Use Only:

STANDARD FORM LLL (REV. 7/1997)
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Attachment 6
eRDS

WHITE COAT WASTE PROJECT

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NIAID Office of Acquisitions Electronic Report Deliverable Submission

National Institutes of Health
Turning Discovery Into Health

User Guide for Vendors

V2018.1.0
April 2018

STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS
WHITE COAT WASTE PROJECT

Obtained via FOIA by WCW Project

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WHITE COAT WASTE PROJECT

STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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eRDS – Electronic Report Deliverable Submission

Vendor Guide

NIH National Institutes of Health
Turning Discovery Into Health

eRDS – Improving your contract deliverables submission process

The electronic Report Deliverable Submission (eRDS) application is a component of NIAID's integrated, secure system for the electronic submission, capture, tracking and review of NIAID contract deliverables. The **eRDS** application allows:

- **Vendors** to easily submit contract deliverables.
- **Procurement Technicians, Contracting Officers Representative, and Contract Specialists/Officer** to track and accept contract deliverables.

Vendor Roles

eRDS has two Vendor roles:

- **Vendor Admin (VA):** the 'lead' Vendor assigned to the contract by the NIAID Contract Specialist (CS). They can create and assign Vendor Submitters (VS) to their contracts, as well as submit deliverables themselves. The CS can create multiple Vendor Admins for a contract if needed.
- **Vendor Submitter (VS):** created by the Vendor Admin to submit deliverables for their contracts. The VA may add multiple Vendor Submitters to their contract as needed.

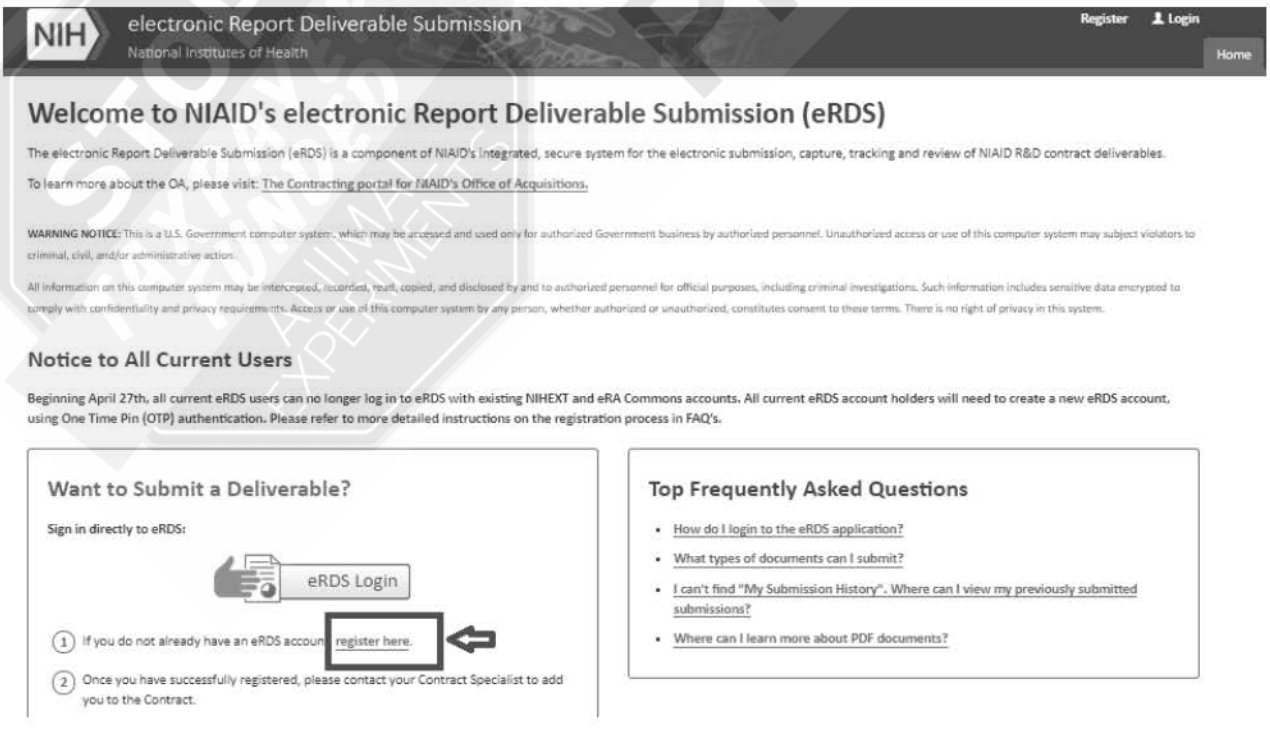
Vendor Registration – How to register for an eRDS account

How to register for an eRDS account - Applies to Vendor Admin and Vendor Submitter

*Note: All Vendors (Vendor Admin/Vendor Submitter) with existing NIH EXT and eRA Commons accounts can **no longer** login to electronic Report Deliverable System. All vendors must have an eRDS account to login.*

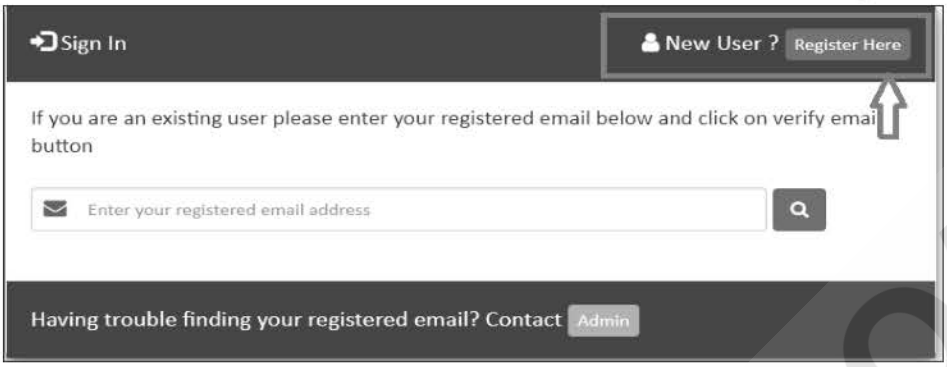
- *Follow the steps to register for an eRDS account:*

1. Go to the eRDS Registration https://erds.niaid.nih.gov/
2. Click on **register here**



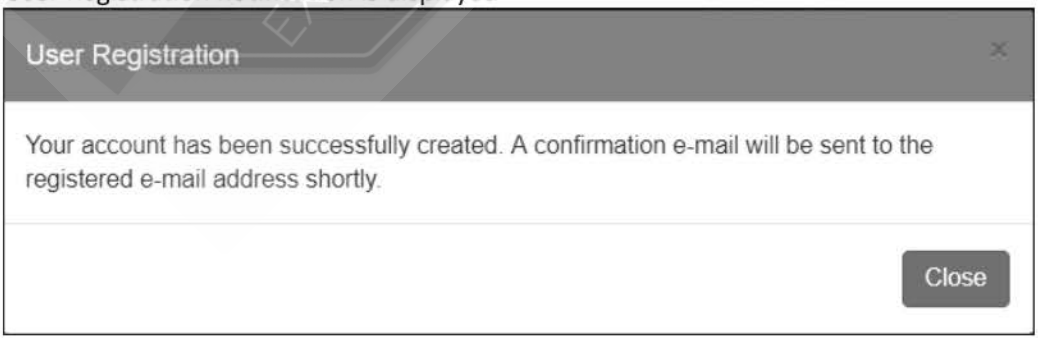
Obtained via FOIA by WCW Project

3. You will be directed to One Time PIN Authentication screen. Locate ' Register Here ' link and click on it.



4. Complete the application and click **'Continue** ' button

5. User Registration notification is displayed



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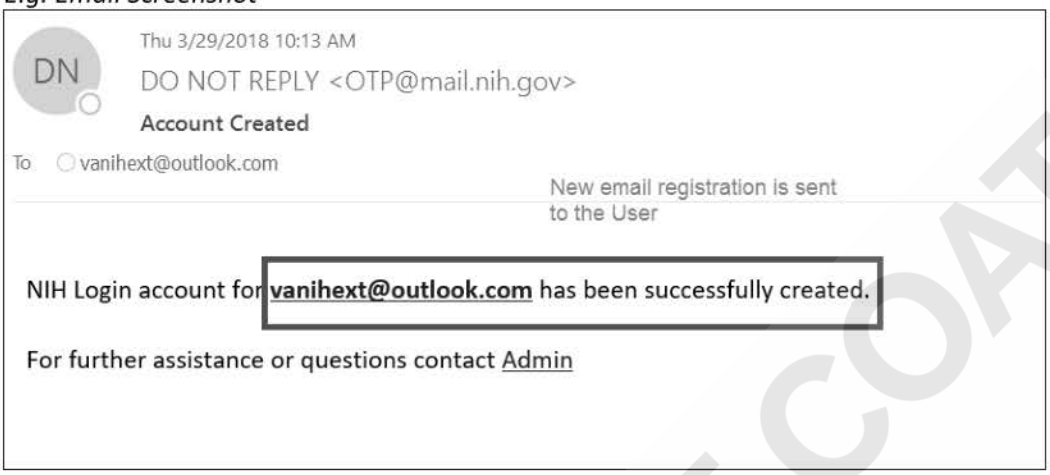
6. User email registration notification is sent that the account had been created
E.g. Email Screenshot



7. Once you receive the email, you need to notify your Contract Specialist that you have competed the account registration for eRDS account with the following Information.
   - ✓ First Name
   - ✓ Last Name
   - ✓ Organization
   - ✓ Contract Number that you need access to
   - ✓ Email used for registration of eRDS account

8. Once Contract Specialist adds you to the contract, you will receive an email notification after which you will be able to log into eRDS to access your Contract and submit deliverables. *Refer to section "**How to login if you have a registered eRDS account**"*

Note: If you try to login to eRDS before Contract Specialist assigns you to the Contract you will see the following message.

"Sorry, you are not associated with any contracts. Please click here to return to Home page."

WHITE COAT WASTE PROJECT
STOP TAXPAYER FUNDED ANIMAL EXPERIMENTS

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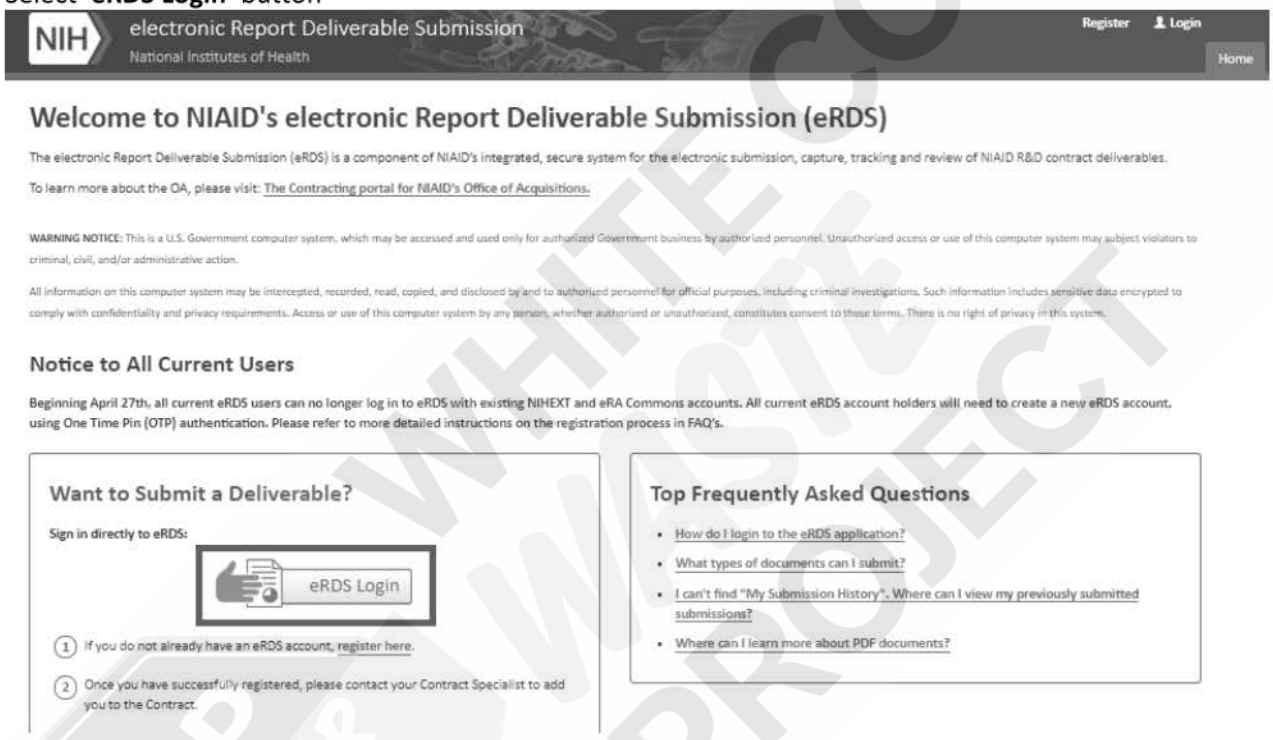
How to login if you have a registered eRDS account - Applies to Vendor Admin and Vendor Submitter

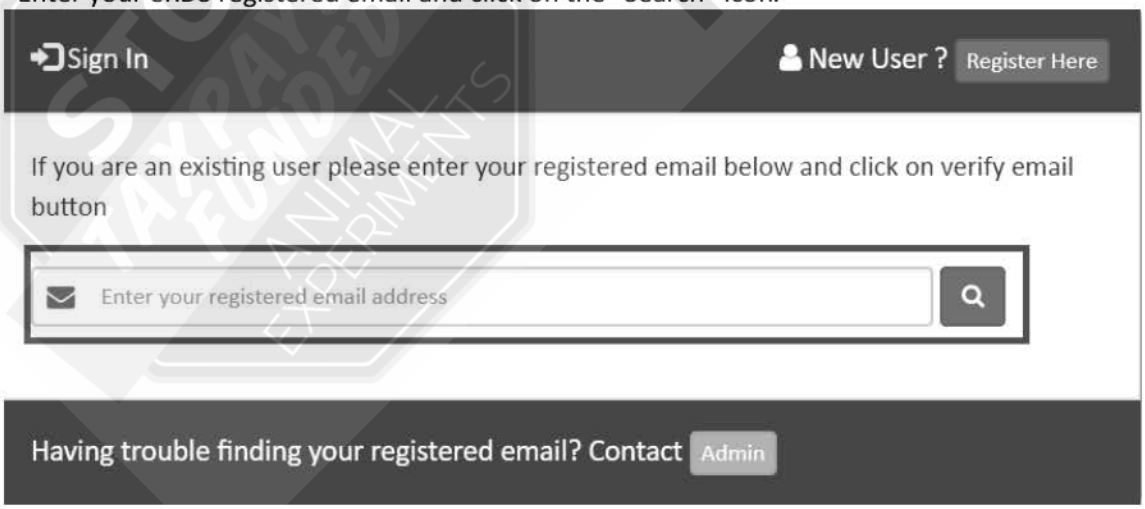
Note: All Vendors (Vendor Admin/Vendor Submitter) with existing NIH EXT and eRA Commons accounts can ***no longer*** *login to electronic Report Deliverable System. You must have an eRDS account to login.*

If you have applied for an eRDS and the Contract Specialist has assigned your account to the Contract, follow the steps to login to the eRDS application. If you have not registered for an eRDS account, please refer to the instructions in the "How to register for an eRDS account and login" section above.

1. Go to the eRDS Registration https://erds.niaid.nih.gov/
2. Select '**eRDS Login'** button



3. Enter your eRDS registered email and click on the "Search" icon.



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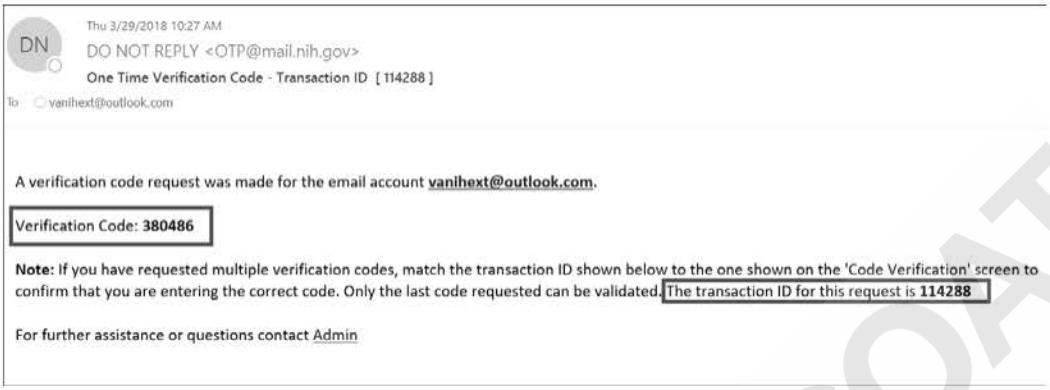
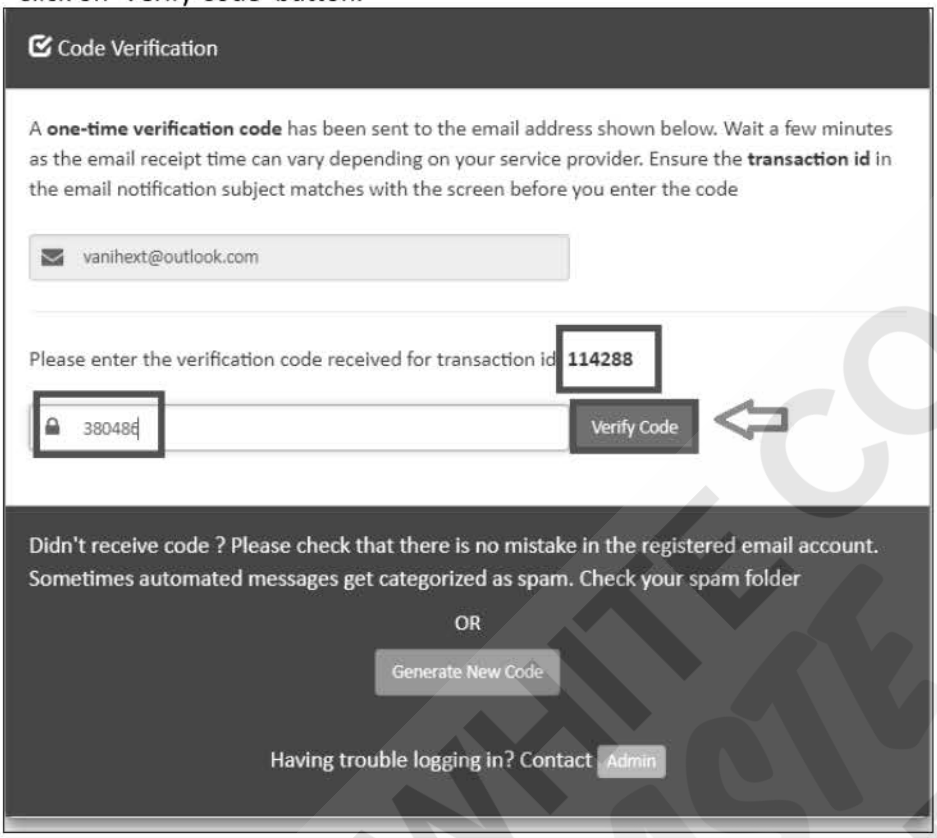
4. The Email with the **one-time verification code** is mailed to the user email address



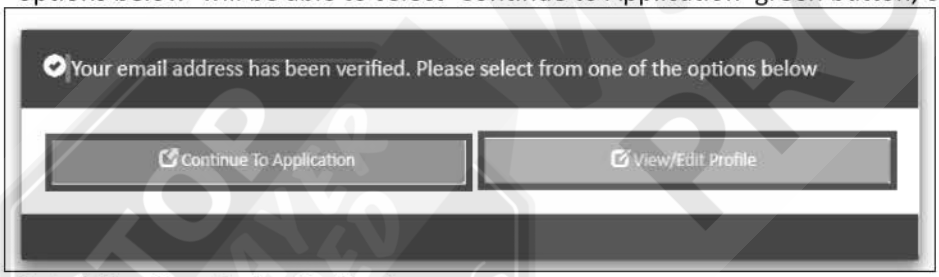
5. Enter the verification code provided in the email on the 'Code Verification' screen. Ensure the transaction ID provided in the email matches the transaction ID provided in the screen.
Note: *The one-time verification code sent to you is valid for the next 8 hours. If you log in within the next 8 hours, you can use the same code to login. If you try to login after 8 hours, the application will automatically send you a new code. Alternatively, if you have issues with login using the existing code, you can click on generate new code button at the bottom of the screen which will automatically send out a new code.*

Obtained via FOIA by WCW Project

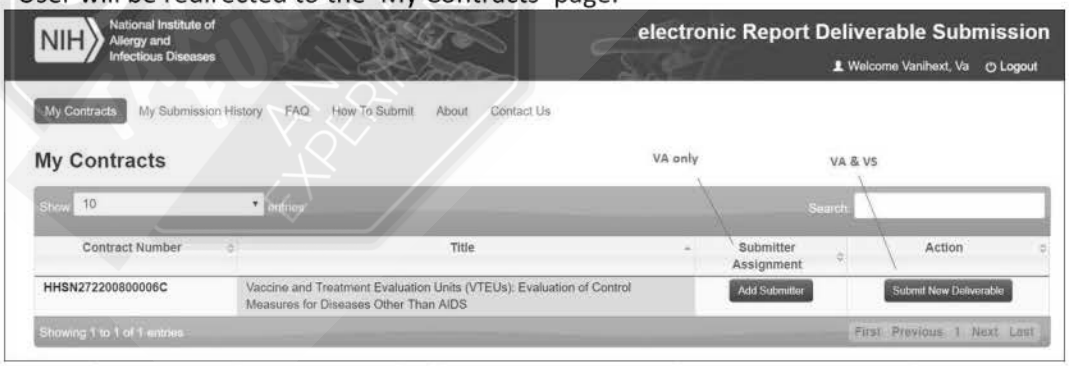
6. Click on 'Verify Code' button.



7. The notification message is displayed: "Your email address has been verified. Please select from one of the options below' will be able to select 'Continue to Application' green button, or select 'View/Edit Profile'



8. Select 'Continue to Application'.
9. User will be redirected to the 'My Contracts' page.



Note: If you try to login to eRDS before Contract Specialist assigns you to the Contract you will see the following message.

"Sorry, you are not associated with any contracts. Please click **here** to return to Home page."

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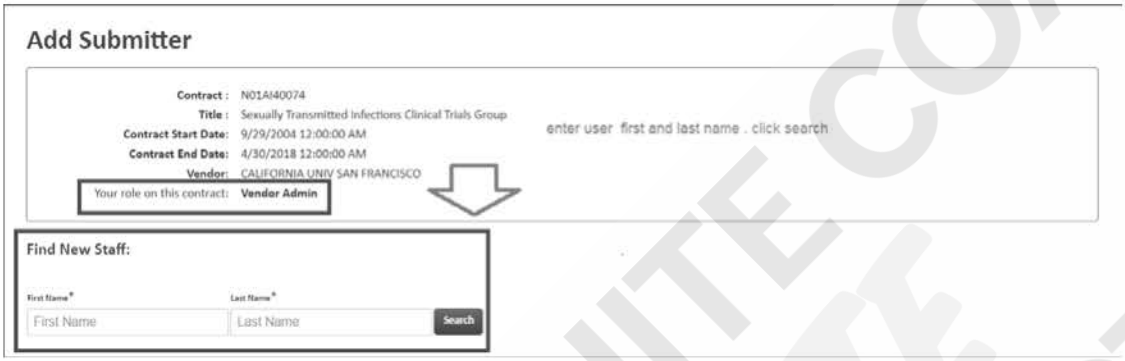
Add Vendor Submitter

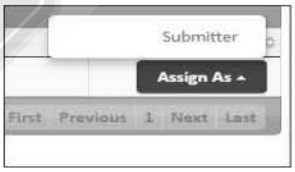
To add a Vendor Submitter to a contract (Vendor Admin <u>ONLY</u>):
*Note: Vendor Admin can add a Vendor Submitter to the Contract to submit deliverables on behalf of the Vendor. Vendor Submitter **must have an eRDS account** before Vendor Admin can add Vendor Submitter to the Contract.*

1. Select the Add Submitter (Add Submitter) button in the "Submitter Assignment" column
2. Enter First and Last Names in the "Find New Staff" fields and click Search (Search)



3. If the user has a registered eRDS account, it will display the result in popup window. If the user does not have a registered eRDS account, then no results will be displayed.
For example:

4. User with Vendor Admin (VA) role can assign Submitter to Contract as a "Submitter", and click 'Close':

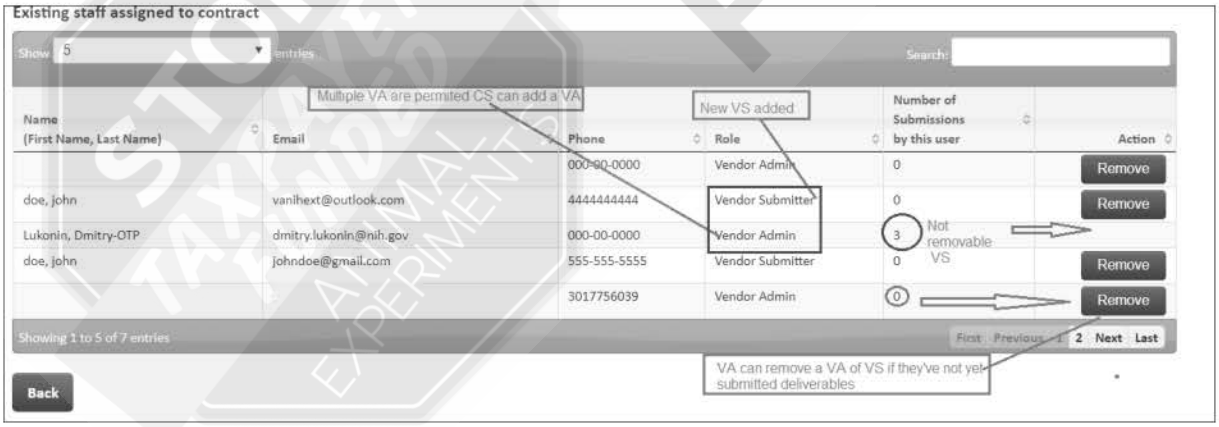


5. Once the VA assigns the New Submitter to a contract, the following message is displayed. User assigned on the contract successfully! Submitter will receive an email notification after which submitter can access the contract and submit deliverables.

Obtained via FOIA by WCW Project

6. If the submitter had already been assigned to the contract and is reassigned again, the system displays the following message. User already assigned on this contract!

7. The Vendor Admin (VA) can remove Vendor Staff(s) including themselves, if they haven't submitted any deliverables yet (a *zero* under 'Number of Submissions by this user' column).
8. Select the Back (Back) button to return to 'My Contracts'



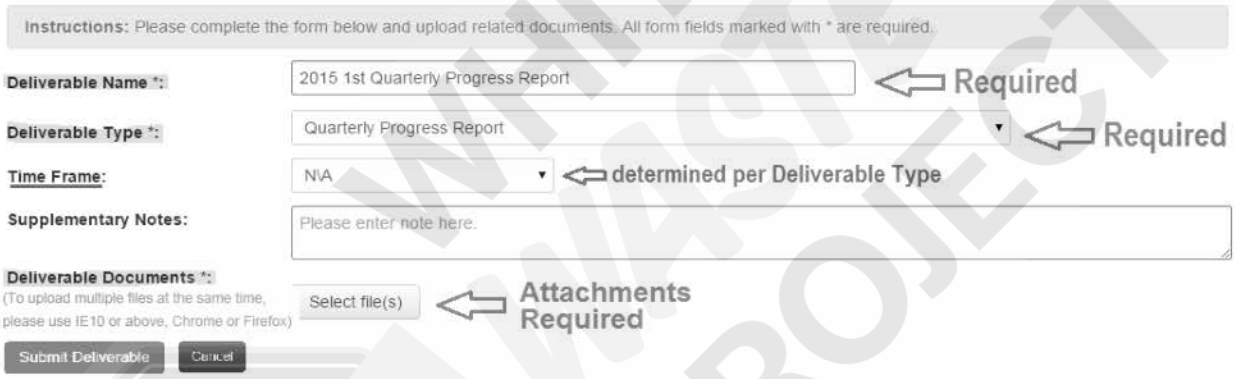
Obtained via FOIA by WCW Project

Submit New Deliverable

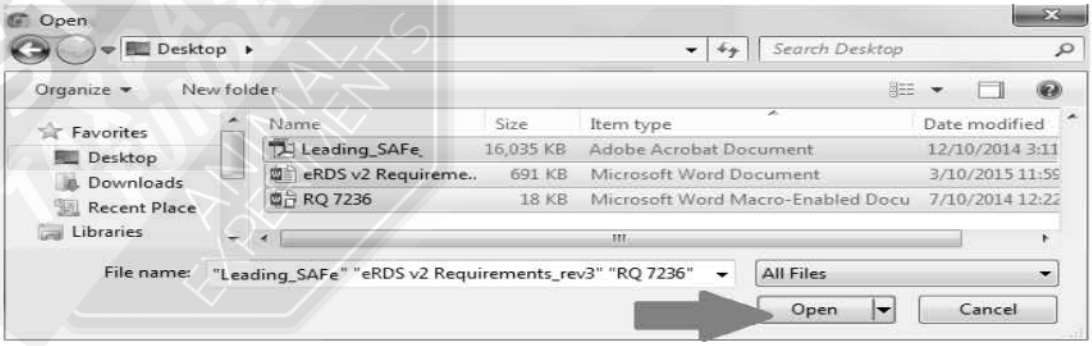
To Submit a New Contract Deliverable:

1. Select your contract's Submit New Deliverable (Submit New Deliverable) button in the "Action" column.

2. Enter the Deliverable's *Name*, *Type, Time Frame* (for recurring reports in the calendar year), and any *Supplementary Notes* as needed:



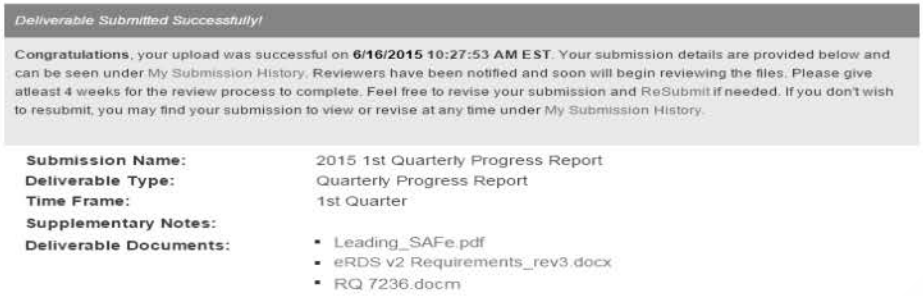
3. Choose Select file(s) (Select Files) to attach one or more documents. Using Internet Explorer 10 and above, Google Chrome or Mozilla Firefox as web browsers will enable user to select multiple files at the same time. Microsoft Office files (word, excel) and Adobe PDF are accepted.
4. Choose "Open" once User have files selected.



5. The attached files display next to Deliverable Documents. Select Submit Deliverable (Submit Deliverable) to complete the submission:

Obtained via FOIA by WCW Project

6. A delivery confirmation screen is displayed with a summary of the delivered content submitted.



7. Upon submission of the deliverable documents user can view the data on 'My Submission History' page.

COR Inspection of Deliverable

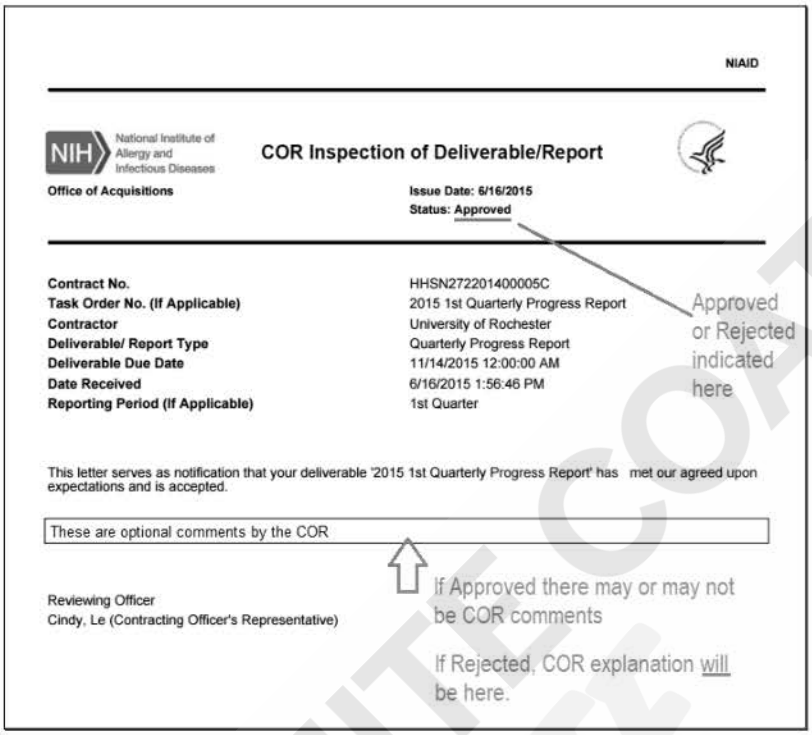
COR Inspection of Deliverable (IOD) report; My Submission History

1. Upon acceptance/rejection of the deliverable documents, user will receive a 'Notice of Status Change' email with an embedded link to eRDS. After login, user will be redirected to 'My Submission History' page.
   - NOTE: if deliverables are rejected, a similar notice is sent

2. On this page, user will see contract's title and number, submission details, and document links, and the COR Inspection of Deliverable Report PDF at the bottom of the details.

3. To review, select the COR Inspection of Deliverable Report PDF to download the document through your web browser.

Obtained via FOIA by WCW Project



NIAID

NIH National Institute of Allergy and Infectious Diseases

COR Inspection of Deliverable/Report

Office of Acquisitions

Issue Date: 6/16/2015
Status: Approved

Approved or Rejected indicated here

Contract No.	HHSN272201400005C
Task Order No. (If Applicable)	2015 1st Quarterly Progress Report
Contractor	University of Rochester
Deliverable/ Report Type	Quarterly Progress Report
Deliverable Due Date	11/14/2015 12:00:00 AM
Date Received	6/16/2015 1:56:46 PM
Reporting Period (If Applicable)	1st Quarter

This letter serves as notification that your deliverable '2015 1st Quarterly Progress Report' has met our agreed upon expectations and is accepted.

These are optional comments by the COR

If Approved there may or may not be COR comments

If Rejected, COR explanation will be here.

Reviewing Officer
Cindy, Le (Contracting Officer's Representative)

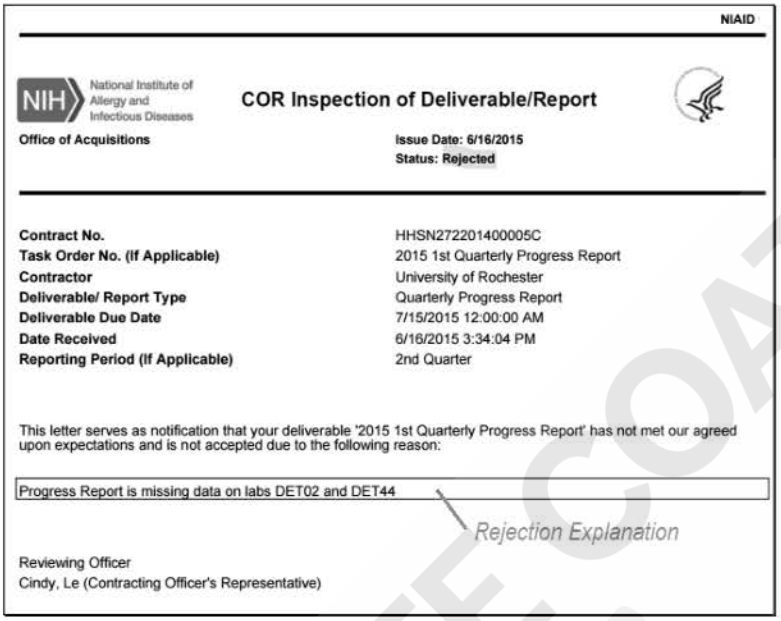
Re-Submission & Alternate Submissions

Re-Submit a Deliverable

1. If user receives a 'Notice of Status Change' email notice from NIAID that the submission was *not accepted* (rejected), select the embedded link in the email notice to go to 'My Submission History'.

2. Under 'My Submission History', the COR Inspection of Deliverable Report PDF will provide an explanation for the rejection.

Obtained via FOIA by WCW Project



NIAID

National Institute of Allergy and Infectious Diseases

COR Inspection of Deliverable/Report

Office of Acquisitions

Issue Date: 6/16/2015
Status: Rejected

Contract No.	HHSN272201400005C
Task Order No. (If Applicable)	2015 1st Quarterly Progress Report
Contractor	University of Rochester
Deliverable/ Report Type	Quarterly Progress Report
Deliverable Due Date	7/15/2015 12:00:00 AM
Date Received	6/16/2015 3:34:04 PM
Reporting Period (If Applicable)	2nd Quarter

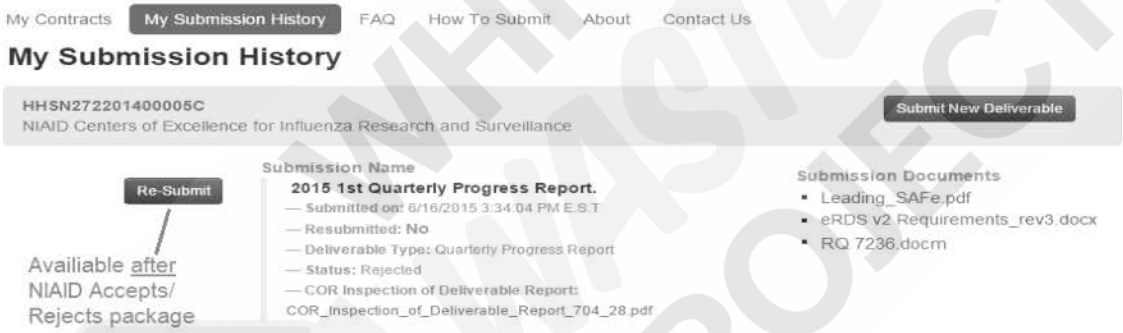
This letter serves as notification that your deliverable '2015 1st Quarterly Progress Report' has not met our agreed upon expectations and is not accepted due to the following reason:

Progress Report is missing data on labs DET02 and DET44

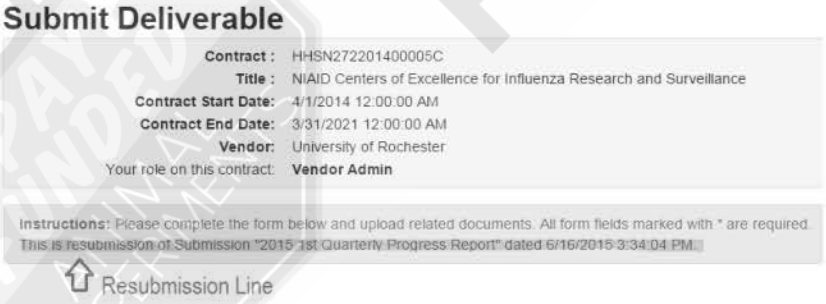
Rejection Explanation

Reviewing Officer
Cindy, Le (Contracting Officer's Representative)

3. User revises the deliverable documents and selects the Re-Submit (Re-Submit) button for revised deliverable resubmission. Click OK button to get past the notification popup window.



4. The Submit Deliverable page is the same for re-submissions, except for an additional instruction line indicating resubmission status. After submission, user will receive the same confirmation messages and email notices



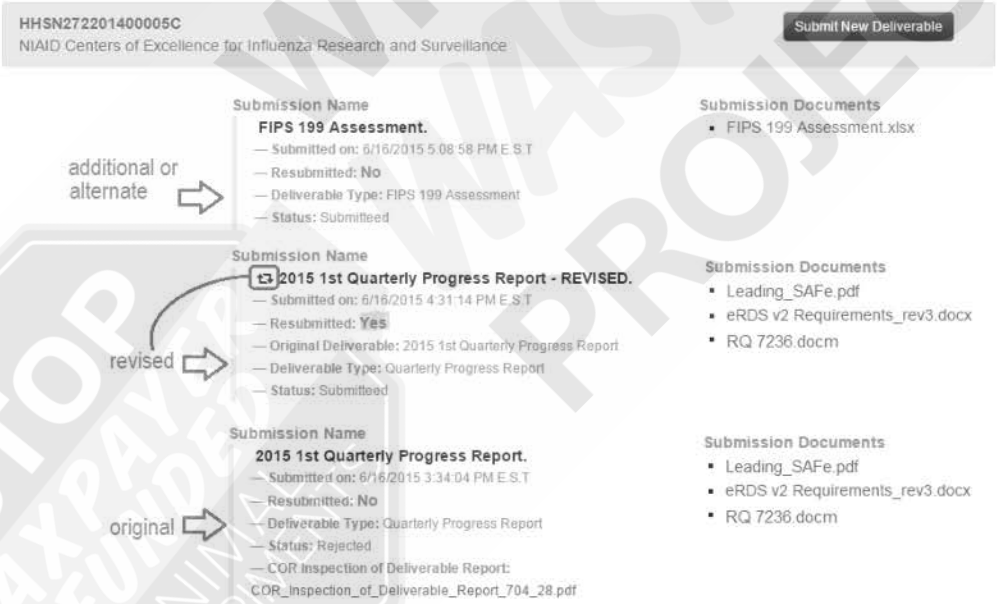
5. Under 'My Submission History', the submission details are updated with the revised submission. The original is also still visible

Obtained via FOIA by WHITE COAT WASTE PROJECT

Submit an Alternate Deliverable

1. If user's contract requires two different types of deliverables, eRDS allows the Vendor to submit a second or 'alternate' deliverable. On the 'My Submission History' page, there is a Submit New Deliverable (Submit New Deliverable) button for each contract. It is available even if the last submission for a given deliverable is still under review and is neither accepted nor rejected yet.

2. Selecting the Submit New Deliverable (Submit New Deliverable) button takes you to the Submit Deliverable page. After submission, the My Submission History page is updated with the new package



Obtained via FOIA by PEER/CCW Project