EXHIBIT A

| AWARD/CONTRACT | 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | RATING | PAGE OF PAGES 1 \| 54 |
|---|---|---|---|
| 2. CONTRACT (Proc. Inst. Ident.) NO. W81XWH20C0066 | 3. EFFECTIVE DATE 19 Jun 2020 | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE | |

| 5. ISSUED BY CODE W81XWH | 6. ADMINISTERED BY (If other than Item 5) CODE |
|---|---|
| USA MED RESEARCH ACQ ACTIVITY<br>820 CHANDLER ST<br>FORT DETRICK MD 21702-5014 | See Item 5 |

| 7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) | 8. DELIVERY [ ] FOB ORIGIN [ X ] OTHER (See below) |
|---|---|
| OPH REX, INC.<br>(b) (6)<br>5643 PARADISE DR #2<br>CORTE MADERA CA 94925-1815 | 9 DISCOUNT FOR PROMPT PAYMENT<br>Net 30 Days |
| | 10 SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM Section G |
| CODE 7JTR0 FACILITY CODE 7JTR0 | |

| 11. SHIP TO/MARK FOR CODE W806YH | 12. PAYMENT WILL BE MADE BY CODE HQ0490 |
|---|---|
| USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232 | DEFENSE FINANCE AND ACCOUNTING SERVICE<br>DFAS- NDY VP GFEBS<br>8899 E 56TH STREET<br>NDIANAPOLIS IN 46249-3800 |

| 13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( ) | 14. ACCOUNTING AND APPROPRIATION DATA See Schedule |
|---|---|

| 15A. ITEM NO. | 15B. SUPPLIES/ SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | SEE SCHEDULE | | | | |
| | | | 15G. TOTAL AMOUNT OF CONTRACT | | $9,873,778.00 |

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

| 17 [ X ] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return 1 copies 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) | 20A. NAME OF CONTRACTING OFFICER<br>MICAELA BOWERS / CONTRACTING OFFICER<br>TEL: (301) 619-21173 EMAIL: Micaela.l.Bowers.civ@mail.mil |
|---|---|
| 19B. NAME OF CONTRACTOR<br>BY _____<br>(Signature of person authorized to sign) | 19C. DATE SIGNED |
| 20B. UNITED STATES OF AMERICA<br>BY (b) (6) | 20C. DATE SIGNED<br>19-Jun-2020 |

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STANDARD FORM 26 (REV 5/2011)
Prescribed by GSA – FAR (48 CFR) 53 214(a)

Section A - Solicitation/Contract Form

CONTRACT SUMMARY:

RESEARCH TITLE: "Targeting sPLA2 for Treatment of Acute Respiratory Distress Syndrome (ARDS) Associated with SARS-COV-2"
TOPIC #: DHA18-002
EGS Log #: 19000053

PRINCIPAL INVESTGATOR: Co-PI - Dr. Matthew Lewin; matt@ophirex.com
Co-PI – Dr. Rebecca Carter; becky@ophirex.com

CONTRACT TYPE: Hybrid - Firm Fixed Price and Cost Plus Fixed Fee
TOTAL CONTRACT VALUE: $9,873,778.00

TERM/SCOPE OF CONTRACT:

PHASE III PERFORMANCE PERIOD: 19 June 2020 through 18 June 2023 (Research ends 18 February 2023). An additional 120 days are provided after the research period has ended on 18 February 2023 for the submission of the Final Technical Report. The Final Technical Report for this Phase III effort is due no later than 18 June 2023.

The scope of this contract encompasses the complete SBIR process to include all Phases of the Award.

SBIR/STTR Data Rights are covered in DFARS clause 252.227-7018.

Assertions have been made in follow-on to DFARS 252-227-7017 "Identification and assertions use, release, or disclosure restriction" and are incorporated as Attachment 3.

ACQUISITION HISTORY:

Phase I was awarded as a Firm Fixed Price (FFP) under contract W81XWH18C0144 on 25 June 2018 against DHA Phase I proposal H181-002-0002 under SBIR Topic DHA18-002, titled: "Broad Spectrum Envenomation Treatment". The award value was $148,509.12 for the period 25 June 2018 through 24 January 2019 (Research ends 24 December 2018).

Phase II was awarded as a Firm Fixed Price (FFP) under contract W81XWH19C0082 on 31 July 2019 against DHA Phase II proposal H2-0440. The award value is $975,495.76 for the period 5 August 2019 through 4 January 2022 (Research ends 4 August 2021).

GOVERNMENT CONTACTS:

Contract Specialist:

U.S. Army Medical Research Acquisition Activity (USAMRAA)
ATTN: FCMR-AAA-SH (Mrs. Donna Blackstone)
820 Chandler Street
Fort Detrick, MD 21702-5014
Voice: 301-619-2276
Email: donna.r.blackstone.civ@mail mil

Contracting Officer:

US Army Medical Research Acquisition Activity (USAMRAA)
ATTN: FCMR-AAA-SH (Ms. Micaela L. Bowers)
820 Chandler Street

Fort Detrick, MD 21702-5014
Voice: 301-619-2173
Email: micaela.l.bowers.civ@mail.mil

Contracting Officer's Representative (COR):

US Army Medical Materiel Development Activity (USAMMDA)
ATTN: (b) (6)
1430 Veterans Drive
Fort Detrick, MD 21702-5014
Voice: (b) (6)
Email: (b) (6)

Section B - Supplies or Services and Prices

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0001 | | [redacted] | (b) (4) | $(b) (4) | $(b) (4) |

SBIR Phase III - Manufacturing Start-Up
FFP
Funding provided for Manufacturing Start-Up Costs for the Oral and IV Drug Product Initiation. (To be invoiced upon award.)
FOB: Destination
PSC CD: AN94

NET AMT $(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000101 | | | | | $0.00 |

Manufacturing Start Up Cost - Funding
FFP
Funding in the amount of $(b) (4) provided to cover manufacturing start up costs for the Oral and IV Drug Product initiation.
PURCHASE REQUEST NUMBER: 0011507230

NET AMT $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150723000001

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0002 | | [redacted] | (b) (4) | $(b) (4) | $(b) (4) |

SBIR Phase III - COVID-ARDS
FFP
The Contractor shall provide all necessary equipment, personnel, facilities and supplies to conduct the SBIR Phase III research objectives in accordance with the Contract Schedule and Contractor's Proposal dated 26 May 2020 and associated Budget dated 8 June 2020, titled: "Targeting sPLA2 for Treatment of ARDS Associated SARS-CoV-2"

Technical Objectives to be completed: 1 (all tasks excluding 1.A.1, 1.B.1 and 1.C.1); 2 (all tasks); 3 (all tasks); and 4) (Tasks A, B, and C) and Management Objectives 1 and 2.

Monthly Technical Progress Reports, Contract Data Requirements List (CDRLs), Other Deliverables, and One Final Technical Report will be required for this Phase III effort as outlined in Statement of Work Section C12.

Assertions have been claimed by the company in follow-up to DFARS 252.227-7017 and are incorporated as Attachment 3.
FOB: Destination
PSC CD: AN94

NET AMT $(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000201 | | | | | $0.00 |

COVID-ARDS - Funding
FFP
Funding in the amount of $(b) (4) applied against CLIN 0002 as SLIN 000201 to be paid in 7 monthly increments of $(b) (4)
PURCHASE REQUEST NUMBER: 0011507230-0002

NET AMT $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150723000002

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0003 | | (b) (4) | (b) (4) | $(b) (4) | $(b) (4) |

SBIR Phase III - COVID-ARDS
FFP
The Contractor shall provide all necessary equipment, personnel, facilities and supplies to conduct the SBIR Phase III research objectives in accordance with the Contract Schedule and Contractor's Proposal dated 26 May 2020 and associated Budget dated 8 June 2020, titled: "Targeting sPLA2 for Treatment of ARDS Associated SARS-CoV-2"

Technical Objectives to be completed: 1 (all tasks excluding 1.A.1, 1.B.1 and 1.C.1); 2 (all tasks); 3 (all tasks); and 4) (Tasks A, B, and C) and Management Objectives 1 and 2.

Monthly Technical Progress Reports, Contract Data Requirements List (CDRLs), Other Deliverables, and One Final Technical Report will be required for this Phase III effort as outlined in Statement of Work Section C12.

Assertions have been claimed by the company in follow-up to DFARS 252.227-7017 and are incorporated as Attachment 3.
FOB: Destination
PSC CD: AN94

NET AMT $(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000301 | | | | | $0.00 |

COVID ARDS - Funding
FFP
Funding in the amount of $(b) (4) applied against CLIN 0003 as SLIN 000301 for be paid in 11 monthly increments of $(b) (4)
PURCHASE REQUEST NUMBER: 0011507230-0002

NET AMT $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150723000003

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0004 | | (b) (4) | (b) (4) | $(b) (4) | $(b) (4) |

SBIR Phase III - COVID-ARDS
FFP
The Contractor shall provide all necessary equipment, personnel, facilities and supplies to conduct the SBIR Phase III research objectives in accordance with the Contract Schedule and Contractor's Proposal dated 26 May 2020 and associated Budget dated 8 June 2020, titled: "Targeting sPLA2 for Treatment of ARDS Associated SARS-CoV-2"

Technical Objectives to be completed: 1 (Subtasks 1.A.1, 1.B.1 and 1.C.1)

Monthly Technical Progress Reports, Contract Data Requirements List (CDRLs), Other Deliverables, and One Final Technical Report will be required for this Phase III effort as outlined in Statement of Work Section C12.

Assertions have been claimed by the company in follow-up to DFARS 252.227-7017 and are incorporated as Attachment 3.
FOB: Destination
PSC CD: AN94

NET AMT $(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000401 | | | | | $0.00 |

COVID-ARDS - Funding
FFP
Funding in the amount of $(b) (4) applied against CLIN 0004 as SLIN 000401 to be paid in 28 monthly increments of $(b) (4)
PURCHASE REQUEST NUMBER: 0011507230

NET AMT $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150723000004

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0005 | | [redacted] | (b) (4) | $(b) (4) | $(b) (4) |

SBIR Phase III - COVID-ARDS
FFP
The Contractor shall provide all necessary equipment, personnel, facilities and supplies to conduct the SBIR Phase III research objectives in accordance with the Contract Schedule and Contractor's Proposal dated 26 May 2020 and associated Budget dated 8 June 2020, titled: "Targeting sPLA2 for Treatment of ARDS Associated SARS-CoV-2"

Technical Objectives to be completed: 1 (Subtasks 1.A.1, 1.B.1 and 1.C.1)

Monthly Technical Progress Reports, Contract Data Requirements List (CDRLs), Other Deliverables, and One Final Technical Report will be required for this Phase III effort as outlined in Statement of Work Section C12.

Assertions have been claimed by the company in follow-up to DFARS 252.227-7017 and are incorporated as Attachment 3.
FOB: Destination
PSC CD: AN94

NET AMT $(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000501 | | | | | $0.00 |

COVID-ARDS - Funding
FFP
Funding in the amount of $(b) (4) applied against CLIN 0005 as SLIN 000501 to be paid in 1 monthly payment.
PURCHASE REQUEST NUMBER: 0011507230

NET AMT $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150723000005

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0006 | | (b) (4) | (b) (4) | | $(b) (4) |

SBIR Phase III-COVID-ARDS Clinical Trial
CPFF
The Contractor shall provide all necessary equipment, personnel, facilities and supplies to conduct the SBIR Phase III research objectives in accordance with the Contract Schedule and Contractor's Proposal dated 26 May 2020 and associated Budget dated 8 June 2020, titled: "Targeting sPLA2 for Treatment of ARDS Associated SARS-CoV-2"

Technical Objective to be completed: Clinical Trial (Task 4C)

Monthly Technical Progress Reports, Contract Data Requirements List (CDRLs), Other Deliverables, and One Final Technical Report will be required for this Phase III effort as outlined in Statement of Work Section C12.

Assertions have been claimed by the company in follow-up to DFARS 252.227-7017 and are incorporated as Attachment 3.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011507230
PSC CD: AN94

| | |
|---|---|
| ESTIMATED COST | $(b) (4) |
| FIXED FEE | $(b) (4) |
| TOTAL EST COST + FEE | $(b) (4) |
| | $(b) (4) |

ACRN AA
CIN: GFEBS001150723000006

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0007 | | 4 | Each | | NSP |

Contractor Manpower Reporting (CMR)
FFP
Provide information for the duration of Phase III performance associated with the input of the Accounting for Contract Services information in the website operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. UIC: W4QFAA; PSC: AN94
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0008 | | 1 | Each | | NSP |

CDRL Exhibit A, A001
FFP
Contract Data Requirements List (CDRL) Exhibit A, Data Item No. A001 - Quality Management Plan (QMP). (NOTE: Deliverable is As Generated and may exceed the quantity of 1.)
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0009 | | 1 | Each | | NSP |

CDRL Exhibit A, A002
FFP
CDRL Exhibit A, Data Item No. A002 - Regulatory Strategy and Development Plan
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0010 | | 1 | Each | | NSP |

CDRL Exhibit A, A003
FFP
CDRL Exhibit A, Data Item No. A003 - cGMP Manufacturing Documentation (NOTE: Deliverable is As Required and may exceed the quantity of 1.)
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0011 | | 1 | Each | | NSP |

CDRL Exhibit A, A004
FFP
CDRL Exhibit A, Data Item No. A004 - FDA Interactions (NOTE: Deliverable is As Required and may exceed the quantity of 1.)
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0012 | | 1 | Each | | NSP |

CDRL Exhibit A, A005
FFP
CDRL Exhibit A, Data Item No. A005 - Pre-Clinical Data
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0013 | | 1 | Each | | NSP |

CDRL Exhibit A, A006
FFP
CDRL Exhibit A, Data Item No. A006 - Clinical Trial Data (NOTE: Deliverable is As Generated and may exceed the quantity of 1.)
FOB: Destination
PSC CD: AN94

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0014 | | 1 | Each | | NSP |

CDRL Exhibit B, B001
FFP
CDRL Exhibit B, Data Item No. B001 - Final Technical Report.
Once the Final Technical Report has been approved by the
COR, the report is to be submitted to DTIC. The contractor shall provide to the Contract Specialist a copy of DTIC's notification that the final report has been received. See DFARS Clause 252.235-7011.

FOB: Destination
PSC CD: AN94

NET AMT

Section C - Descriptions and Specifications

STATEMENT OF WORK:

C1. Background:

C1.1 Small Business Innovation Research (SBIR) Program:

C1.1.1. SBIR Program Background: The US Army Medical Research and Development Command, in support of the Department of Defense Small Business Innovation Research (SBIR), has taken part in the Defense Health Agency (DHA) Program Broad Agency Announcement (BAA) for FY 2018.1. Objectives of the solicitation included stimulating technological innovation in the private sector, strengthening the role of the small business in meeting Federal research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, increasing the commercial application of DOD-supported research results, and improving their return on investment from Federally-funded research for economic and social benefits to the Nation. The Federal SBIR Program is mandated by Public Laws 97-219, 99-443, 102-564 (STTR) and 106-554.

C1.1.2 SBIR Phased Program:

C1.1.2.1. Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR program. The contractor shall concentrate on that research or development which will significantly contribute to providing the scientific or technical feasibility of the approach or concept and which would be a prerequisite to further DOD support in Phase II.

C1.1.2.2. Phase II awards are made to firms with approaches that appear sufficiently promising as a result of Phase I. Phase II awards typically cover 2-5 man-years of effort and to cover a period generally not to exceed 24 months, subject to negotiation. The number of Phase II awards will depend upon Phase I results and availability of funds. Phase II is the principal research or development effort; it will require a more comprehensive proposal, outlining the proposed effort, as explained below. Agencies may offer special SBIR awards, such as Phase II Enhancement awards, that supplement or extend Phase II awards. The Phase II Enhancement awards differ from base Phase II in that they require third party matching of the SBIR funds. Each such supplemental award must be linked to a base Phase II award.

C1.1.2.3. Under Phase III, it is intended that non-Federal capital be used by the small business to pursue commercial applications of the research or development. Also, under Phase III, Federal agencies may award non-SBIR funded follow-on contracts for products or processes, which meet the mission needs of those agencies.

C2. Targeting sPLA2 for Treatment of Acute Respiratory Distress syndrome Associated with SARs-CoV-2:

C2.1. Acute respiratory distress syndrome (ARDS) is associated with physical, physiological and infectious insults such as those caused by blunt trauma, barotrauma and, most currently and urgently of interest, pandemic SARS-CoV-2 infections. Mortality in patients with SARS-CoV-2 infection that develops into ARDS is extremely high even with optimal therapy, and long-term morbidity is severe. Coronaviruses in the SARS group (e.g. SAR-CoV-1, -2 and MERS) have mortality rates linked to ARDS approach 50% in patients with co-morbidities. Ophirex seeks to conduct clinical studies of treatment with Varespladib to reduce progression to and severity of COVID-19 associated ARDS. COVID-19 mortality rates are strongly linked to ARDS which, in turn, is also strongly correlated with phospholipase A2 (sPLA2) elevation. SPLA2 is a critical mediator of normal inflammatory response associated with infection, but systemic overexpression of sPLA2 feeds into cytokine overexpression and Cytokine Release Syndrome [AKA Systemic Inflammatory Response Syndrome (SIRS) or "cytokine storm"], which frequently results in ARDS. Critically, elevations in sPLA2 result in enzymatic degradation of surfactant and even greater release of factors, including TNF-a, TNF-B and IL-6. These cycles of inflammation and surfactant destruction act synergistically to the point at which the innate immune response to insult becomes lethally maladaptive. Uniquely, inhibition of sPLA2 can restore immune homeostasis and enhance respiratory function via prevention of reversal of cytokine storm and direct protection of surfactant from enzymatic degradation.

C2.3. The U.S. Army Medical Materiel Development Activity (USAMMDA) Warfighter Protection and Acute Care Project Management Office (WPAC PMO) seeks to utilize an innovative and experienced biopharmaceutical company to advance development and achieve FDA licensure of an inhibitor of SAR-CoV-2-related ARDS that is easy to use and shelf-stable that will protect the Force (population 18-55 years of age).

C3. Objectives:

To conduct the primary focus of this work, Ophirex will support a clinical study to determine the safety and efficacy of Varespladib to control or prevent COVID-19 associated ARDs as an addition to standard of care. Additional work to support this primary focus includes cGMP manufacturing of drug products, non-clinical validation of Varespladib efficacy, and regulatory and product development strategy through Investigational New Drug (IND) approval. Final expected timelines proposed in the Integrated Master Schedule will depend on pandemic patient load, clinical outcome and regulatory environment.

C3.1. Technical Objectives:

C3.1.1. Manufacturing of cGMP drug product of quantity and quality that is suitable and appropriate for use in clinical studies to demonstrate safety and efficacy against SARS-CoV-2 associated ARDS in humans.

C3.1.1.1. Manufacturing with stability of Oral Solid Dose (OSD) drug product batch

C3.1.1.1.1. Oral solid dose stability

C3.1.1.2. Manufacturing with stability of sterile injectable IV lyophilized drug product batch

C3.1.1.2.1. Lyophilized sterile IV product Stability

C3.1.1.3. Reduction of reliance on just in time manufacturing for Key Raw Materials of LY333013 and LY315920

C3.1.2. Non-clinical validation of sPLA2 as a therapeutic target and efficacy of Varespladib to reduce lung tissue inflammation, spare surfactant, and reduce ARDS

C3.1.2.1. Validation of Varespladib efficacy in animal model of coronavirus infection

C3.1.3. Advancement of Regulatory and Product Development strategy through filing and approval of IND application

C3.1.3.1. Quality Program support for GMP, GLP and GCP

C3.1.3.2. Develop Regulatory and Product Development Strategy for SARS-CoV-2 application

C3.1.3.3. Regulatory Filings up to and including an approved IND

C3.1.4. Clinical study in patients with suspected or confirmed SARS-CoV-2 to determine safety and efficacy of Varespladib to reduce incidence and severity of ARDS in conjunction with SOC

C3.1.4.1. Develop Clinical Strategy & Product Development

C3.1.4.2. Human Research Protection Office (HRPO) and Institutional Review Board (IRB) reviews

C3.1.4.3. Conduct Clinical Study

C3.2. Management Objectives:

C3.2.1. Management of Ophirex Integrated Product Development Team, including core and sub-teams supporting Non-Clinical, Clinical, CMC, Quality, and Commercialization work.

C3.2.2. Program management of both the primary contractual requirements supporting this SBIR III proposal as well as maintenance of distinct work streams between SARS-CoV-2 SBIR III and separate Broad-Spectrum snakebite antidote SBIR III proposed work.

C4. Scope of Work:

C4.1. Research Title: "Targeting sPLA2 for Treatment of ARDS Associated with SARs-CoV-2"

C4.2. The contractor shall, for the research period of 32 months plus an additional 120 days are provided for the submission of the final technical report following contract award, furnish the necessary personnel, facilities, equipment, and supplies to conduct Phase III of the study cited above. The Statement of Work, as contained in the Contractor's Technical Proposal dated 26 May 2020 in response to the DHA SBIR Broad Agency Announcement (BAA) No. 2018.1, Topic DHA18-002, is incorporated into this award. The contractor shall perform the following concurrent tasks to meet the objectives laid out in section C3 with detailed description outlined in Attachment 1:

C4.2.1. Technical Objective 1:

C4.2.1.1. Task 1.A. Manufacturing with stability of Oral Solid Dose (LY333013) Drug Product

C4.2.1.1.1. Subtask 1.A.1 Oral Solid Dose Stability

C4.2.1.1.2. Task 1.A. Milestones and Deliverables

C4.2.1.2. Task 1.B. Manufacturing with stability of sterile, injectable lyophilized Varespladib drug product (LY315920)

C4.2.1.2.1. Subtask 1.A.2 Lyophilized Sterile IV Product Stability

C4.2.1.2.2. Milestones and Deliverables

C4.2.1.3. Task 1.C. Reduction of reliance on just in time manufacturing for Key Raw Materials of LY333013 and LY315920

C4.2.1.3.1. Milestones and Deliverables

C4.2.2. Technical Objective 2:

C4.2.2.1. Task 2.A. Validation of efficacy in an animal model of coronavirus

C4.2.2.2. Milestones and Deliverables

C4.2.3. Technical Objective 3:

C4.2.3.1. Task 3.A. Quality Program support for GMP, GLP and CGP

C4.2.3.1.1. Milestones and Deliverables

C4.2.3.2. Task 3.B. Development of Regulatory and Product Development Strategy for Varespladib as Therapeutic for SARS-CoV-2 Associated ARDS

C4.2.3.2.1. Milestones and Deliverables

C4.2.3.3. Task 3.C. Regulatory Filings Up to and Including IND

C4.2.3.3.1. Milestones and Deliverables

C4.2.4. Technical Objective 4:

C4.2.4.1. Task 4.A. Clinical Strategy and Protocol Development

C4.2.4.1.1. Milestones and Deliverables

C4.2.4.2. Task 4.B. Human Research Protection Office (HRPO) and Institutional Review Board (IRB) Approval

C4.2.4.2.1. Milestones and Deliverables

C4.2.4.3. Task 4.C. Clinical Study

C4.2.4.3.1. Milestones and Deliverables

C4.2.5. Management Objectives:

C4.2.5.1. Integrated Product Development Team (IPT) Management

C4.2.5.2. Contract Management

C4.2.5.2.1. Milestones and Deliverables

C5. PLACE OF PERFORMANCE

C5.1. Place of performance includes the following locations:

C5.1.1. Prime: Ophirex, Inc., 5643 Paradise Drive, #2, Corte Madera, California, 94925

C5.1.2. Subcontractor: (b) (4)

C5.1.2.1. Subcontractor: (b) (4)

C5.1.2.2. Subcontractor: (b) (4)

C5.1.2.3. Subcontractor: (b) (4)

C5.1.2.4. Subcontractor: (b) (4)

C5.1.3. Subcontractor: (b) (4)

C5.1.4. Subcontractor: (b) (4)

C5.1.5. Subcontractor: (b) (4)

C5.1.6. Consultants: (b) (4)

C5.1.7. Consultants: (b) (4)

C6. Quality Assurance:

C6.1. Oversight of contractor performance shall be in compliance with the Quality Assurance Surveillance Plan (QASP), found at Attachment 2 to this contract.

C7. RESERVED

C8. Contractor Identification:

C8.1. When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

C8.2. While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications

C9. Key Personnel:

C9.1. The following positions have been identified to be filled by Key Personnel proposed for this award.

Position Title: Co-Principal Investigator/Chief Scientist/Chief Medical Officer
Co-Principal Investigator/Chief Development Officer

C9.2. The approved Personnel identified to fill the Key Personnel positions shall be utilized as necessary to fulfill the requirements of this contract.

C9.3. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or change in employment conditions (e.g. termination, change in position, etc.). In any of these events, the contractor shall promptly notify the Contracting Officer in writing and provide the information required by paragraph C7.4 below.

C9.4. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). Any proposed substitute or replacement key personnel shall have qualifications comparable to the individual being replaced, taking into account the requirements of the SOW. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

C9.5. If any of the listed Key Personnel are subcontractor personnel, the contractor shall flow down the substance of this instruction in any subcontract which is awarded in support of this contract.

C10. CO-PRINCIPAL INVESTIGATOR’S:

The Co-Principal Investigator's shall be continuously responsible for the conduct of the research project. The contractor shall obtain the Contracting Officer's approval to change one or both of the Co-Principal Investigator's or to continue the research work during a continuous period in excess of three months without the participation of both approved Co-Principal Investigator's. This contract is based on the Co-Principal Investigator's devoting the number of hours proposed in the approved budget to the project over the term of the contract. The contractor shall advise the Contracting Officer if the Co-Principal Investigator's will, or plans to, revise the level of effort estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

C11. General Requirements:

C11.1. PROHIBITION OF USE OF HUMAN SUBJECTS

C11.1.1. Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, shall not begin until the USAMRDC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRDC ORP, under separate notification to the contractor. Written approval from the USAMRDC ORP is also required for any subcontractor that will use funds from this contract to conduct research involving human subjects.

C11.1.2. Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRDC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRDC. Research records shall be stored in a confidential manner in accordance with FAR 52.224-2.

C11.1.3. The contractor is required to adhere to the following reporting requirements:

C11.1.4. Submission of substantive modifications to the protocol, continuing review documentation, and the final report as outlined in the USAMRDC ORP approval memorandum.

C11.1.5. Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the contractor, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRDC ORP.

C11.1.6. The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRDC ORP.

C11.1.7. Non-compliance with these terms and conditions may result in withholding of payments and/or the termination of the contract. The USAMRDC ORP Human Research Protection Office submission instructions can be accessed at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo**.**

C11.2. PROHIBITION OF USE OF HUMAN CADAVERS

C11.2.1. Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under this contract shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrdc.amedd.army mil/index.cfm/collaborate/research_protections/hrpo).

C11.2.2. The USAMRDC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other hrpo@mail.mil ) for this policy. Approval must be obtained from the USAMRDC ORP. Contractors must coordinate with the Contracting Officer Representative (COR) to ensure that proper approvals are obtained. ORP will issue written approvals to begin under separate notification to the contractor. Written approval to proceed from the USAMRDC ORP is also required for any subcontractor that will use funds from this award to conduct RDT&E, education or training involving human cadaveric specimens.

C11.2.3. Contractors must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the USAMRDC ORP. Contractors must maintain complete records of the activity.

C11.2.4. The USAMRDC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

C11.2.5. Non-compliance with these terms and conditions may result in withholding of payments and/or the termination of the contract.

C11.3. PROHIBITION OF USE OF LABORATORY ANIMALS

C11.3.1. Notwithstanding any other terms and conditions contained in this contract or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRDC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this contract will be issued in the form of an approval letter from the USAMRDC ACURO to the contractor. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, the contractor must maintain, and upon request from ACURO, submit animal usage information.

C11.3.2 Non-compliance with any of these terms and conditions may result in withholding of payment and/or the termination of the contract.

C11.3.3 The Animal Care and Use Office requirements can be accessed at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro.

C11.4. INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT:

C11.4.1. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

C11.4.2. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which US Army Medical Research and Development Command funds have been provided or requested.

C11.4.3. The contractor agrees to:

C11.4.3.1. Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;

C11.4.3.2. Comply with its own administrative process;

C11.4.3.3. Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;

C11.4.3.4. Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and

C11.4.3.5. Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

C11.4.4. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:

C11.4.4.1. An immediate health hazard is involved;

C11.4.4.2. There is an immediate need to protect Federal funds or equipment;

C11.4.4.3. A probability exists that the alleged incident will be reported publicly; or

C11.4.4.4. There is a reasonable indication of possible criminal violation.

C11.5. USE OF TECHNICAL REFERENCE FACILITY:

To the extent practical the Contractor shall utilize the technical reference facilities of the Defense Technical Information Center (DTIC) for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. The DTIC headquarters office is located at 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218. Information can also be obtained via the Internet at https://discover.dtic.mil or via the toll-free number for the DTIC help desk, 1-800-225-3842. To the extent practical, all other sources, whether or not Government controlled, should be consulted for the same purpose.

C11.6. FINANCIAL INSTABILITY, INSOLVENCY, BANKRUPTCY OR RECEIVERSHIP:

C11.6.1. Contractor will immediately notify the USAMRAA Contracting Officer of the occurrence of the following events:

C11.6.1.1. the contractor's financial instability that would negatively impact performance of this contract;

C11.6.1.2. the contractor or contractor's parent company's filing of a voluntary case seeking liquidation or reorganization under the Bankruptcy Act;

C11.6.1.3. the contractor's consent to the institution of an involuntary case under the Bankruptcy Act against the contractor or contractor's parent company;

C11.6.1.4. the filing of any similar proceeding for or against the contractor or contractor's parent company, or its consent to, the dissolution, winding-up or readjustment of the contractor's debts, appointment of a receiver, conservator, trustee, or other officer with similar powers over the organization, under any other applicable state or federal law; or

C11.6.1.5. the recipient's insolvency due to its inability to pay its debts generally as they become due.

C11.6.2. Such notification shall be in writing and shall:

C11.6.2.1. specifically set out the details of the occurrence of an event referenced in paragraph a;

C11.6.2.2. provide the facts surrounding that event; and

C11.6.2.3. provide the impact such event will have on the research and development being funded by this contract.

C11.6.3. Upon the occurrence of any of the five events described in the first paragraph, the Government reserves the right to review contractor's performance to determine if there are significant deficiencies or concerns that would undermine the government's investment in Contractor's work. The Government reserves the right to impose additional requirements, as needed, including:

C11.6.3.1. change the payment method;

C11.6.3.2. institute payment controls, and

C11.6.3.3. require additional reporting requirements. In addition, should any of the five events described in the first paragraph occur, the Government may elect that Contractor transfer possession, ownership and sponsorship/ holdership of any Regulatory Application or intellectual property resulting from this contract in accordance with the procedure and conditions set forth in the clause entitled "Regulatory Rights of Product Development Failures (2012)" incorporated herein.

C11.6.4. Failure of the Contractor to comply with this term may be considered a grounds for the termination of this contract.

C11.7. REGULATORY RIGHTS IN EVENT OF PRODUCT DEVELOPMENT FAILURES

C11.7.1. This contract includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this contract will result in the submission of an investigational new drug application (IND) to the FDA, with subsequent approval of the IND, for a Treatment of Acute Respiratory Distress Syndrome (ARDS) Associated with SARS-CoV-2 or the "Technology." The Contractor is the sponsor of the IND that controls the research under this contract. As the sponsor of the IND (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the IND. This provision protects the return on research and development investment made by the Army Medical Research and Development Command (USAMRDC).

C11.7.2. (b) (4) [redacted]:

a. (b) (4) [redacted]

b. (b) (4) [redacted]

(1) (b) (4) [redacted]

(2) (b) (4) [redacted].

(3) (b) (4) [redacted].

c. The terms of this provision and its derivative obligations:

(1) (b) (4) [redacted];

(2) (b) (4) [redacted];

(3) (b) (4) [redacted];

(4) (b) (4) [redacted]

C11.7.3. The Contractor shall provide FDA submissions, communications, and interactions to USAMMDA as required in Contract Data Requirements List (CDRL), Exhibit A, Data Item A004, CLIN 0011, titled R&D of Medical Products Regulated by the U.S. FDA (DI-TCSP-82040).

C11.8. INDIRECT RATE CAP

In accordance with the Basis of Estimates dated 15 May 2020 and the Final Revised Cost Volume dated 8 June 2020, Opherix, Inc. has stated that "(b) (4) [redacted]

C11.9. FOREIGN NATIONALS

C11.9.1 If Foreign Nationals are utilized, it is the company's responsibility to comply with all governing Federal International Traffic in Arms Regulations (ITAR) and applicable section(s) of the associated Broad Agency Announcement (BAA).

C12. Deliverables:

| No. | Deliverable | Distribution | Initial | Subsequent | Comments |
|---|---|---|---|---|---|
| 1 | IMS | COR | With Proposal | NLT 30 days after award | See Section 3 description for updates to the IMS |
| 2 | CWBS | COR | With Proposal | NLT 30 days after award | Include updates in monthly report as needed |
| 3 | Team Meetings | N/A | Kick-off meeting at the time of contract award | As required, at least monthly | |
| 4 | CDRL-Exhibit A-A001<br>CLIN 0008<br>Quality Manufacturing Plan (QMP) | COR | NLT 45 days after award | N/A | Include updates in monthly report as needed |
| 5 | CDRL-Exhibit A-A002<br>CLIN 0009<br>Regulatory Strategy and Development Plan (RDP) | COR | NLT 45 days after award | N/A | Include updates in monthly report as needed |
| 6 | CDRL-Exhibit A-A003<br>CLIN 0010<br>cGMP Manufacturing Documentation | COR | Within 5 days of report generation or receipt | Deliver all subsequent documents within 5 days of generation or receipt | Include updates in monthly report as needed |
| 7 | CDRL-Exhibit A-A004<br>CLIN 0011<br>Regulatory documentation and FDA submissions | COR | At least 5 days prior to submission | Within 5 days of receipt from FDA | See description |
| 8 | CDRL-Exhibit A-A005<br>CLIN 0012<br>Non-clinical Study Documentation | COR | NLT 60 days after award | Upon ACURO approval (if required) and study completion | Include updates in monthly report as needed |
| 9 | Issue Summary Reports | COR | Within 5 days of breach identification | Report all subsequent breaches within | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | 5 days of identification | |
| 10 | Monthly Technical Progress Reports | COR | NLT 45 days after award | NLT 15th of each month | |
| 11 | Spend Plan | COR | NLT 30 days after award | NLT 15th of each month | |
| 12 | CDRL-Exhibit A-A006<br>CLIN 0013<br>Clinical Study Documentation including Closeout Report | COR | NLT 45 days after award | Upon IRB approval, amendment approval, and study completion | Include updates in monthly report as needed |
| 13 | CDRL-Exhibit B-B001<br>CLIN 0014<br>Final Technical Report | COR, KO | Within 120 days following end of Phase III research period | N/A | Required by SBIR Policy |
| 14 | Patent/Invention Reporting DFARS 252.227-7039 | KO, iEdison | As outlined in the clause | As outlined in the clause | DFARS Requirement |

C12.1. Contractor Manpower Reporting (CMR):

C12.1.1. The contractor shall report ALL contractor labor hours (including subcontractor labor) required for performance of services provided under this contract for the US Army Medical Research and Development Command (USAMRDC) via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: *www.ecmra.mil*. Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year.

C12.1.2. The four Service components user accounts and system data were merged and transferred to the new consolidated Enterprise Contractor Manpower Reporting Application (ECMRA) effective 1 October 2017 at *www.ecmra.mil*.

C12.1.3. Contractors may direct questions to the new ECMRA Support Desk at dod.ecmra.support.desk@mail mil or obtain detailed instructions from the CMR Contractor Manpower Reporting User Guide available on the new ECMRA website www.ecmra mil.

C12.1.4. The Order Data tab on the CMRA Contractor Data Entry website asks for the "Requiring Activity Unit Identification Code" (UIC). This is the UIC of the USAMRDC or other USAMRAA Supported activity or organization (such as DHS), the Requiring Activity that would be performing the mission if not for the contractor. This is not necessarily the Contracting Office, Contracting Administrative Office, or Funding Source. The UIC is not the same as the Department of Defense Activity Address Code (DODAAC).

C12.1.5. The UIC of the Requiring Activity for this contract is W4QFAA; FSC: AN94; NAICS: 541715

C12.2. Technical Reporting Requirements:

C12.2.1. Monthly Technical Progress Reports

C12.2.1.1. The contractor shall submit a Monthly Technical Progress Report covering work accomplished during each month of contract performance. It shall be brief, factual, and informal, and shall be prepared in accordance with the following:

C12.2.1.1.1. Cover containing:

C12.2.1.1.1.1. Contract number and title

C12.2.1.1.1.2. Type of report, sequence number of report, and period of performance being reported

C12.2.1.1.1.3. Contractor's name, address, and telephone number

C12.2.1.1.1.4. Principal Investigator

C12.2.1.1.1.5. Date of publication

C12.2.1.1.1.6. Contracting Officer's Representative (COR)

C12.2.1.1.2. Section I – Introduction and Project Summary (Purpose and Scope of Research Effort). A brief introduction covering the purpose and scope of the research effort (one paragraph summary).

C12.2.1.1.3. Section II – Progress

C12.2.1.1.3.1. Overall Progress Summary. A brief description of overall progress to date for the reporting period (one-two paragraphs summary).

C12.2.1.1.3.2. Individual Task Progress. A separate description for each task or other logical segment of work on which effort was expended during the report period, briefly describing the work that has been performed. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. List all tasks associated with the approved Statement of Work (SOW) including those with no activity performed for the period and status stating as such (i.e. have not started, no work conducted this period, started, delayed, % completed, etc.).

C12.2.1.1.4. Section III - Problems and Changes

C12.2.1.1.4.1. Problems Encountered. A description of current problems that may impede performance, including impact on expenditures, along with proposed corrective action. Report any changes (e.g. staff addition/removal/FTE reduction/increase, approaches, etc.) that happened and why. Note some changes require Contracting Officer's review and expressed written approval through a formal award modification before implementation.

C12.2.1.1.4.2. Problems Anticipated. A description of anticipated problems that have a potential to impede progress and/or impact expenditures, and what corrective action is planned should the problem materialize. Report any changes (e.g. staff, approaches, etc.) planned and why. Note some changes require Contracting Officer's review and expressed written approval through a formal award modification before implementation.

C12.2.1.1.5. Section IV - Next Month Actions. A brief description of work to be performed during the next reporting period for each task. If no work is planned for a task then state so and why if appropriate.

C12.2.1.1.6. Section V - Administrative Comments - Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.

C12.2.1.1.7. Section VI – Research Protocols and Regulatory Status

C12.2.1.1.7.1. Protocol Status. List each protocol planned for the project including title, protocol identifiers (i.e. IACUC number, ACURO number, name of regulatory review board, etc.), type of animals, number of animals, protocol PI, protocol site, etc., and note status of each (e.g. in development, submitted to regulatory agency such as IACUC, ACURO, FDA for review, approval date with name of regulatory authority, date of continuing review or rewrite review, amendments with brief statement of the changes and its status such as submitted and/or approved by which regulatory authority, etc.)

C12.2.1.1.7.2. Adverse Events. Describe any adverse events and actions taken.

C12.2.1.1.8. Section VII - A Gantt Chart showing actual progress versus scheduled progress.

C12.2.1.2. Monthly Technical Progress Reports: The first monthly report will be due 40 days after the start date of the period of performance (10 days after completion of the first 30 days of performance) and then monthly thereafter.

C12.2.1.3. Monthly Technical Progress Reports and Invoice Submission. The Monthly Technical Progress Reports and Invoices shall be submitted electronically to https://ebrap.org for review prior to submission through Wide Area Workflow (WAWF) for Payment. The COR shall have five (5) calendar days to provide comment to the contractor. If the COR does not provide comment within 5 days of submission, the contractor may submit their invoice via WAWF.

C12.3. Deliverable 1 - Integrated Master Schedule. The contractor shall provide an Integrated Master Schedule (IMS) depicting all contract activities linked to the WBS level, as applicable. The IMS shall contain all critical and high- risk efforts identified by the contractor or Government to ensure these are realistically planned and executable. The IMS shall include activities of major subcontractors and suppliers, as applicable. All tasks/ activities in the IMS shall be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program under the agreement.

C12.3.1. The initial IMS shall be provided with the proposal. Provide an IMS update with the monthly status report only if changes in schedule have occurred or are anticipated to occur. Provide the IMS in PDF format indicating monthly task progress, percent completion, and schedule acceleration/slippage. The IMS shall include the approved baseline schedule and the actual schedule.

C12.3.2. Draft changes to the IMS, specifically program level 3 or above milestones or the critical path, shall be submitted to the government for approval. The government will respond with comments or approval 10 business days following receipt of draft changes. A final IMS with incorporated changes shall be submitted 5 business days after receipt of Government comment**s.**

C12.4. Deliverable 2 - Contract Work Breakdown Structure. The initial submission shall be provided with the proposal at a four-level WBS with costs and schedule (top level is program, level 2 is phase, level 3 are major tasks, level 4 are subordinate tasks). For lowest task level, show breakdown for labor, material, and other indirect costs.

C12.4.1. The Contract WBS (CWBS) shall be provided 30 days after award to the appropriate levels reflecting the deliverables for each task and updated annually or 30 calendar days after a SOW modification affecting the CWBS.

C12.4.2. The Government review/approval will be provided within 10 calendar days after receipt of each submittal. The contractor shall provide a final updated CWBS within 5 calendar days after receipt of Government comments/approval.

C12.5. Deliverable 3 - Team Meetings. The contractor shall engage in monthly teleconferences with the Government, beginning with the kick-off meeting at the time of contract award. The date and time of recurring meetings will be agreed upon by the Government and the contractor and ad hoc meetings shall be agreed upon as necessary. The Government will provide dial-in information and an agenda prior to the meeting; the contractor shall submit requests for specific agenda items three (3) days in advance of the meeting. The Government will record the meeting and provide meeting minutes to all participants.

C12.6. Deliverable 4 - Quality Management Plan. (CDRL Exhibit A-A001, DI-TCSP-82040) The contractor shall provide a QMP NLT 45 days after contract award and updates shall be included in the monthly progress reports. The QMP shall describe plans for the drug substance manufacturing process, process development, quality oversight, deviation reporting process, audits, cGMP compliance, and control/qualification/validation of all processes, facilities, equipment, raw materials, and assays. The QMP should include plans for tests

required for human use to include: sterility, stability, and toxicology. Issues and questions from the QMP shall be discussed at the monthly teleconference.

C12.7. Deliverable 5 - Regulatory Strategy and Development Plan (RDP). (CDRL Exhibit A-A002, DI-TCSP-82040) The contractor shall provide a RDP NLT 45 days after contract award and updates shall be included in the monthly progress reports. The RDP shall describe the regulatory pathway, target product profile, and specific plans to meet regulatory objectives. The Plan shall include items listed by the cited DID Section 2a, 1-2 (Drugs and Biologics--Regulatory Strategy and RDP). Issues and questions from the Regulatory Strategy shall be discussed at the monthly teleconference and outlined in the monthly report.

C12.8. Deliverable 6 - GMP manufacturing documentation. (CDRL Exhibit A-A003, DI-TCSP-82040) Copies of the documentation of the cGMP manufacturing of the drug product shall be delivered to the Government within 5 days of receipt or generation by the Contractor. Documentation to be delivered shall include items listed in Section 2e (Drugs and Biologics -- Manufacturing) of the DID DI-TCSP-82040. Issues and questions from cGMP manufacturing or release for human use shall be discussed at the monthly teleconference and outlined in the monthly report.

C12.9. Deliverable 7 - Regulatory Documentation and FDA submissions. (CDRL Exhibit A-A004, DI-TCSP-82040) FDA submissions and communications include those items listed in the cited DID, Section 2b (Drugs and Biologics-FDA Interactions). This includes documentation regarding IND submission. For all Submission Packets, Contractor shall provide one draft copy and one final copy. For all other FDA Interactions, only a final copy is required. Items submitted to FDA by the Contractor shall be delivered to the Government at least 5 days prior to submission. Items received by the Contractor from the FDA shall be delivered to the Government within 5 days of receipt. Delivery schedule should be in agreement with the Integrated Master Schedule. Issues and questions from all FDA Interactions shall be discussed at the monthly teleconference and/or outlined in the monthly progress report.

C12.10. Deliverable 8 - Non-clinical Study Documentation. (CDRL Exhibit A-A005, DI-TCSP-82040) The Contractor shall submit a draft of the Experimental Design Plan/protocol within 60 business days after contract award in a format agreed upon by the contractor and the Government at the time of contract award. A final version shall be delivered at the time of experiment execution or IACUC submission (if required). If animal work is required, copies of IACUC and ACURO communication and decisions shall be delivered within 5 days of receipt by the Contractor. Progress, issues and questions from the pre-clinical tests and studies shall be discussed at the monthly teleconference and outlined in the monthly report. The final report of the study findings shall be delivered to the Government at the time of contract award.

C12.11. Deliverable 9 - Issue Summary Report(s): The Contractor shall provide details of any serious breach of plans (causing at least 3 month delay, 5% increase in cost or impaired performance attribute) as Issue Summary Report, as needed, within five (5) days of identifying the breach. The contractor shall report get-well plans and risk log updates to include risk mitigation strategies.

C12.12. Deliverable 10 - Monthly Technical Progress Reports. The contractor shall submit monthly technical progress reports in accordance with the format included in the Deliverable Section, Paragraph C12.2.1, of the contract.

C12.13. Deliverable 11 - Spend Plan. The Contractor shall provide a Spend Plan which details how the Contractor expects to incur and invoice for costs against the contract. The Spend Plan shall detail costs to be incurred monthly by fiscal year (1 October - 30 September) and by contract year, starting with the first month of the contract period of performance. The Spend Plan total shall match with the total costs proposed for the entire task order in the Cost/Pricing Sheet. The Spend Plan shall be updated as necessary. The Contractor shall report actual progress against the Spend Plan in the Monthly Report.

C12.14. Deliverable 12 - Clinical Study Documentation (CDRL Exhibit A-A006, DI-TCSP-82040) The contractor shall provide a Clinical Study Plan, including the draft clinical protocol and related documents as listed in the cited DID Section 2d (Drugs and Biologics--Clinical Trials), within 45 days after the contract is

awarded in a format agreed upon by the contractor and the Government at that time. The final version of the protocol shall be delivered at the time of IRB submission. Updates and amendments to the protocol shall be delivered within 5 days of submission. Copies of IRB and HRPO communication and decisions shall be delivered within 5 days of receipt by the contractor. Progress, issues and questions from the clinical trial shall be discussed at the monthly teleconference and outlined in the monthly report. The final clinical study report of the study findings shall be delivered to the Government upon completion of data analysis in a format agreed upon by the contractor and the Government at the time of contract award.

C12.15. Deliverable 13 - Final Technical Report (CDRL Exhibit B-B001, DI-MISC-80048) Final Technical Report shall be submitted within 120 calendar days after the "research ends" date for the Phase III effort. In accordance with DFARS clause 252.235-7011, the Final Technical Report shall be submitted to the Defense Technical Information Center (DTIC) upon the COR's approval of the report. The contractor shall provide to the Contract Specialist an electronic copy of DTIC's notification that the final report has been received.

C12.16. Deliverable 14 - Patent/Invention Reporting:

C12.16.1. SBIR/STTR awardees must report inventions to the component within two months of the inventor's report to the awardee. The reporting of inventions may be accomplished by submitting paper documentation, including fax, or through the Edison Invention Reporting System at www.iedison.gov.

C12.16.2. Closeout report. A final DD Form 882 is required, whether or not the contractor is reporting an invention. Submit the report within three months of end of the period of performance. List all inventions made during the period of performance or state "none," as applicable. The award will not be closed until the contractor has met all reporting requirements. Submit all DD Form 882 reports electronically to the Contract Specialist shown in Section A, Contract Summary.

C12.17. CONTRACTOR PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS)

C12.17.1. A CPARS assesses a contractor's performance and provides a record, both positive and negative, on a given contractor during a specific period of time. Each assessment is based on objective facts and supported by program and contract management data, such as cost performance reports, customer comments, quality reviews, technical interchange meetings, financial solvency assessments, construction/production management reviews, contractor operations reviews, functional performance evaluations, and earned contract incentives. Performance evaluations are transmitted into the Past Performance Information Retrieval System (PPIRS) which is used by government agencies to assess contractor past performance for future acquisitions. The contractor shall appoint a Contractor Representative (CR) and provide this information to the Contracting Officer (KO) within 10 calendar days of award. The contractor POC shall have the authority to comment on the CPAR assessment on behalf of their company and within the timeframes established.

C12.17.2. A CPARS assessment must be completed within 120 calendar days after the evaluation. Evaluations are sent to PPIRS within 14 calendar days after the government Assessing Official (AO) has submitted the rating. If the CR has not concurred/non- concurred with the rating; PPIRS will show the government evaluation as "Contractor Comment Pending Review". The CR has a total of 60 calendar days to concur/non- concur with the assessment. After 60 days, the CR can either concur/non-cur. The CR has the authority to: access the Government evaluation; review/comment/concur or non-concur with the assessment within 60 calendar days after notification of the government's assessment. The CR has the right to request a meeting (in writing) with the government within 7 calendar days of notification of an assessment. Once the government and the CR complete the evaluation; an automatic update will be sent to PPIRS and visible for Source Selection. If the CR fails to respond within 60 days, the assessment will be finalized. Training for CPARS can be found on the CPARS website: https://www.cpars.gov/index.htm.

C12.17.3. To access CPARS, the contractor must have a Public Key Infrastructure (PKI). It is suggested an ECA certificate of Medium Assurance should be purchased. This should be a Department of Defense identity certificate, not an e-mail certificate.

Section D - Packaging and Marking

PACKAGING AND MARKING:

a. Packaging shall be standard commercial to ensure acceptance by common carriers for safest delivery to destination unless otherwise specified in the specifications or descriptions of the items.

b. All shipping or mailing containers shall be marked showing Contract No. W81XWH20C0066 and the destination shall be the address shown in Section F.

## INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

| CLIN | INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|---|
| 0001 | Destination | Government | Destination | Government |
| 000101 | N/A | N/A | N/A | N/A |
| 0002 | Destination | Government | Destination | Government |
| 000201 | N/A | N/A | N/A | N/A |
| 0003 | Destination | Government | Destination | Government |
| 000301 | N/A | N/A | N/A | N/A |
| 0004 | Destination | Government | Destination | Government |
| 000401 | N/A | N/A | N/A | N/A |
| 0005 | Destination | Government | Destination | Government |
| 000501 | N/A | N/A | N/A | N/A |
| 0006 | Destination | Government | Destination | Government |
| 0007 | Destination | Government | Destination | Government |
| 0008 | Destination | Government | Destination | Government |
| 0009 | Destination | Government | Destination | Government |
| 0010 | Destination | Government | Destination | Government |
| 0011 | Destination | Government | Destination | Government |
| 0012 | Destination | Government | Destination | Government |
| 0013 | Destination | Government | Destination | Government |
| 0014 | Destination | Government | Destination | Government |

CLAUSES INCORPORATED BY REFERENCE

| | | |
|---|---|---|
| 52.246-4 | Inspection Of Services--Fixed Price | AUG 1996 |
| 52.246-5 | Inspection Of Services Cost-Reimbursement | APR 1984 |
| 52.246-8 | Inspection Of Research And Development Cost Reimbursement | MAY 2001 |

## DELIVERY INFORMATION

| CLIN | DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|---|
| 0001 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |
| 000101 | N/A | N/A | N/A | N/A |
| 0002 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |
| 000201 | N/A | N/A | N/A | N/A |
| 0003 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |
| 000301 | N/A | N/A | N/A | N/A |
| 0004 | N/A | N/A | N/A | N/A |
| 000401 | N/A | N/A | N/A | N/A |
| 0005 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |
| 000501 | N/A | N/A | N/A | N/A |

| | | | | |
|---|---|---|---|---|
| 0006 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |
| 0007 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0008 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0009 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0010 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0011 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0012 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0013 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |
| 0014 | POP 19-JUN-2020 TO 18-JUN-2023 | N/A | (SAME AS PREVIOUS LOCATION)<br>FOB: Destination | W806YH |

CLAUSES INCORPORATED BY REFERENCE

| | | |
|---|---|---|
| 52.242-15 | Stop-Work Order | AUG 1989 |
| 52.247-34 | F.O.B. Destination | NOV 1991 |

Section G - Contract Administration Data

## ACCOUNTING AND APPROPRIATION DATA

AA: 097202020210130000184105525202 55 R.0038743.3.3.5 6100.9000021001
COST CODE: A97CJ
AMOUNT: $(b) (4)

| ACRN | CLIN/SLIN | CIN | AMOUNT |
|---|---|---|---|
| AA | 000101 | GFEBS001150723000001 | $(b) (4) |
| | 000201 | GFEBS001150723000002 | $(b) (4) |
| | 000301 | GFEBS001150723000003 | $(b) (4) |
| | 000401 | GFEBS001150723000004 | $(b) (4) |
| | 000501 | GFEBS001150723000005 | $(b) (4) |
| | 0006 | GFEBS001150723000006 | $(b) (4) |

CLAUSES INCORPORATED BY FULL TEXT

252.232-7003 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS AND RECEIVING REPORTS (DEC 2018)

(a) Definitions. As used in this clause--

Contract financing payment means an authorized Government disbursement of monies to a contractor prior to acceptance of supplies or services by the Government.

(1) Contract financing payments include--

(i) Advance payments;

(ii) Performance-based payments;

(iii) Commercial advance and interim payments;

(iv) Progress payments based on cost under the clause at Federal Acquisition Regulation (FAR) 52.232-16, Progress Payments;

(v) Progress payments based on a percentage or stage of completion (see FAR 32.102(e)), except those made under the clause at FAR 52.232-5, Payments Under Fixed-Price Construction Contracts, or the clause at FAR 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(vi) Interim payments under a cost reimbursement contract, except for a cost reimbursement contract for services when Alternate I of the clause at FAR 52.232-25, Prompt Payment, is used.

(2) Contract financing payments do not include--

(i) Invoice payments;

(ii) Payments for partial deliveries; or

(iii) Lease and rental payments.

Electronic form means any automated system that transmits information electronically from the initiating system to affected systems.

Invoice payment means a Government disbursement of monies to a contractor under a contract or other authorization for supplies or services accepted by the Government.

(1) Invoice payments include--

(i) Payments for partial deliveries that have been accepted by the Government;

(ii) Final cost or fee payments where amounts owed have been settled between the Government and the contractor;

(iii) For purposes of subpart 32.9 only, all payments made under the clause at 52.232-5, Payments Under Fixed-Price Construction Contracts, and the clause at 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(iv) Interim payments under a cost-reimbursement contract for services when Alternate I of the clause at 52.232-25, Prompt Payment, is used.

(2) Invoice payments do not include contract financing payments.

Payment request means any request for contract financing payment or invoice payment submitted by the Contractor under this contract or task or delivery order.

Receiving report means the data prepared in the manner and to the extent required by Appendix F, Material Inspection and Receiving Report, of the Defense Federal Acquisition Regulation Supplement.

(b) Except as provided in paragraph (d) of this clause, the Contractor shall submit payment requests and receiving reports in electronic form using Wide Area WorkFlow (WAWF). The Contractor shall prepare and furnish to the Government a receiving report at the time of each delivery of supplies or services under this contract or task or delivery order.

(c) Submit payment requests and receiving reports to WAWF in one of the following electronic formats:

(1) Electronic Data Interchange.

(2) Secure File Transfer Protocol.

(3) Direct input through the WAWF website.

(d) The Contractor may submit a payment request and receiving report using methods other than WAWF only when--

(1) The Contractor has requested permission in writing to do so, and the Contracting Officer has provided instructions for a temporary alternative method of submission of payment requests and receiving reports in the contract administration data section of this contract or task or delivery order;

(2) DoD makes payment for commercial transportation services provided under a Government rate tender or a contract for transportation services using a DoD-approved electronic third party payment system or other exempted vendor payment/invoicing system (e.g., PowerTrack, Transportation Financial Management System, and Cargo and Billing System);

(3) DoD makes payment on a contract or task or delivery order for rendered health care services using the TRICARE Encounter Data System; or

(4) The Governmentwide commercial purchase card is used as the method of payment, in which case submission of only the receiving report in WAWF is required.

(e) Information regarding WAWF is available at https://wawf.eb.mil/.

(f) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

(End of clause)

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

N/A – Contractor Manpower Reporting and Contract Data Requirements Lists (CDRLs) are "Not Separately Priced"

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

Firm Fixed Price (FFP) – CLINS 0001 through 0005 - Invoice 2in1
Cost Plus Fixed Fee (CPFF) – CLIN 0006 – Cost Voucher

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Firm Fixed Price – Invoice 2in1 - Routing Data Table*

| *Field Name in WAWF* | *Data to be entered in WAWF* |
|---|---|
| Pay Official DoDAAC | HQ0490 |
| Issue By DoDAAC | W81XWH |
| Admin DoDAAC | W81XWH |
| Inspect By DoDAAC | W806YH |
| Ship To Code | W806YH |
| Ship From Code | N/A |
| Mark For Code | N/A |
| Service Approver (DoDAAC) | N/A |
| Service Acceptor (DoDAAC) | W806YH |
| Accept at Other DoDAAC | N/A |
| LPO DoDAAC | N/A |

| | |
|---|---|
| DCAA Auditor DoDAAC | N/A |
| Other DoDAAC(s) | N/A |

Cost Plus Fixed Fee – Cost Voucher - Routing Data Table*

| *Field Name in WAWF* | *Data to be entered in WAWF* |
|---|---|
| Pay Official DoDAAC | HQ0490 |
| Issue By DoDAAC | W81XWH |
| Admin DoDAAC | W81XWH |
| Inspect By DoDAAC | W806YH |
| Ship To Code | W806YH |
| Ship From Code | N/A |
| Mark For Code | N/A |
| Service Approver (DoDAAC) | HAA051 |
| Service Acceptor (DoDAAC) | W806YH |
| Accept at Other DoDAAC | N/A |
| LPO DoDAAC | N/A |
| DCAA Auditor DoDAAC | HAA051 |
| Other DoDAAC(s) | N/A |

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Contract Specialist: Mrs. Donna Blackstone – donna r.blackstone.civ@mail.mil

NOTE: Please include the COR and Contract Specialist on the invoice submission notification.

(2) Contact the WAWF helpdesk at (b) (6) if assistance is needed.

(End of clause)

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

| | | |
|---|---|---|
| 52.202-1 | Definitions | NOV 2013 |
| 52.203-3 | Gratuities | APR 1984 |
| 52.203-5 | Covenant Against Contingent Fees | MAY 2014 |
| 52.203-6 | Restrictions On Subcontractor Sales To The Government | SEP 2006 |
| 52.203-7 | Anti-Kickback Procedures | MAY 2014 |
| 52.203-8 | Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity | MAY 2014 |
| 52.203-10 | Price Or Fee Adjustment For Illegal Or Improper Activity | MAY 2014 |
| 52.203-12 | Limitation On Payments To Influence Certain Federal Transactions | OCT 2010 |
| 52.203-13 | Contractor Code of Business Ethics and Conduct | OCT 2015 |
| 52.203-17 | Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights | APR 2014 |
| 52.204-4 | Printed or Copied Double-Sided on Postconsumer Fiber Content Paper | MAY 2011 |
| 52.204-7 | System for Award Management | OCT 2018 |
| 52.204-10 | Reporting Executive Compensation and First-Tier Subcontract Awards | OCT 2018 |
| 52.204-13 | System for Award Management Maintenance | OCT 2018 |
| 52.204-19 | Incorporation by Reference of Representations and Certifications. | DEC 2014 |
| 52.204-23 | Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities. | JUL 2018 |
| 52.204-25 | Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. | AUG 2019 |
| 52.209-6 | Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment | OCT 2015 |
| 52.209-10 | Prohibition on Contracting With Inverted Domestic Corporations | NOV 2015 |
| 52.210-1 | Market Research | APR 2011 |
| 52.215-2 | Audit and Records--Negotiation | OCT 2010 |
| 52.215-8 | Order of Precedence--Uniform Contract Format | OCT 1997 |
| 52.215-10 | Price Reduction for Defective Certified Cost or Pricing Data | AUG 2011 |
| 52.215-12 | Subcontractor Certified Cost or Pricing Data | OCT 2010 |
| 52.215-14 | Integrity of Unit Prices | OCT 2010 |
| 52.215-15 | Pension Adjustments and Asset Reversions | OCT 2010 |
| 52.215-17 | Waiver of Facilities Capital Cost of Money | OCT 1997 |
| 52.215-18 | Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions | JUL 2005 |
| 52.215-19 | Notification of Ownership Changes | OCT 1997 |
| 52.215-23 | Limitations on Pass-Through Charges | OCT 2009 |
| 52.219-6 (Dev) | Notice of Total Small Business Set-Aside (DEVIATION 2020-O0008). | MAR 2020 |
| 52.219-8 | Utilization of Small Business Concerns | OCT 2018 |
| 52.219-14 (Dev) | Limitations on Subcontracting (DEVIATION 2020-O0008) | MAR 2020 |
| 52.219-28 | Post-Award Small Business Program Rerepresentation | MAY 2020 |
| 52.222-3 | Convict Labor | JUN 2003 |
| 52.222-21 | Prohibition Of Segregated Facilities | APR 2015 |

| | | |
|---|---|---|
| 52.222-26 | Equal Opportunity | SEP 2016 |
| 52.222-35 | Equal Opportunity for Veterans | OCT 2015 |
| 52.222-36 | Equal Opportunity for Workers with Disabilities | JUL 2014 |
| 52.222-37 | Employment Reports on Veterans | FEB 2016 |
| 52.222-40 | Notification of Employee Rights Under the National Labor Relations Act | DEC 2010 |
| 52.222-50 | Combating Trafficking in Persons | JAN 2019 |
| 52.222-54 | Employment Eligibility Verification | OCT 2015 |
| 52.223-6 | Drug-Free Workplace | MAY 2001 |
| 52.223-18 | Encouraging Contractor Policies To Ban Text Messaging While Driving | AUG 2011 |
| 52.225-13 | Restrictions on Certain Foreign Purchases | JUN 2008 |
| 52.227-1 | Authorization and Consent | DEC 2007 |
| 52.227-1 Alt I | Authorization And Consent (Dec 2007) - Alternate I | APR 1984 |
| 52.227-2 | Notice And Assistance Regarding Patent And Copyright Infringement | DEC 2007 |
| 52.227-3 | Patent Indemnity | APR 1984 |
| 52.229-3 | Federal, State And Local Taxes | FEB 2013 |
| 52.232-2 | Payments Under Fixed-Price Research And Development Contracts | APR 1984 |
| 52.232-9 | Limitation On Withholding Of Payments | APR 1984 |
| 52.232-17 | Interest | MAY 2014 |
| 52.232-20 | Limitation Of Cost | APR 1984 |
| 52.232-22 | Limitation Of Funds | APR 1984 |
| 52.232-23 | Assignment Of Claims | MAY 2014 |
| 52.232-25 | Prompt Payment | JAN 2017 |
| 52.232-25 Alt I | Prompt Payment (Jan 2017) Alternate I | FEB 2002 |
| 52.232-33 | Payment by Electronic Funds Transfer--System for Award Management | OCT 2018 |
| 52.232-39 | Unenforceability of Unauthorized Obligations | JUN 2013 |
| 52.232-40 | Providing Accelerated Payments to Small Business Subcontractors | DEC 2013 |
| 52.233-1 | Disputes | MAY 2014 |
| 52.233-3 | Protest After Award | AUG 1996 |
| 52.233-3 Alt I | Protest After Award (Aug 1996) - Alternate I | JUN 1985 |
| 52.233-4 | Applicable Law for Breach of Contract Claim | OCT 2004 |
| 52.242-1 | Notice of Intent to Disallow Costs | APR 1984 |
| 52.242-3 | Penalties for Unallowable Costs | MAY 2014 |
| 52.242-4 | Certification of Final Indirect Costs | JAN 1997 |
| 52.242-13 | Bankruptcy | JUL 1995 |
| 52.243-1 | Changes--Fixed Price | AUG 1987 |
| 52.243-1 Alt V | Changes--Fixed-Price (Aug 1987) - Alternate V | APR 1984 |
| 52.243-2 | Changes--Cost-Reimbursement | AUG 1987 |
| 52.243-2 Alt V | Changes--Cost-Reimbursement (Aug 1987) - Alternate V | APR 1984 |
| 52.244-5 | Competition In Subcontracting | DEC 1996 |
| 52.244-6 | Subcontracts for Commercial Items | AUG 2019 |
| 52.245-1 | Government Property | JAN 2017 |
| 52.245-9 | Use And Charges | APR 2012 |
| 52.246-23 | Limitation Of Liability | FEB 1997 |
| 52.246-25 | Limitation Of Liability--Services | FEB 1997 |
| 52.247-63 | Preference For U.S. Flag Air Carriers | JUN 2003 |
| 52.249-2 | Termination For Convenience Of The Government (Fixed-Price) | APR 2012 |
| 52.249-6 | Termination (Cost Reimbursement) | MAY 2004 |
| 52.249-9 | Default (Fixed-Priced Research And Development) | APR 1984 |

| | | |
|---|---|---|
| 52.249-14 | Excusable Delays | APR 1984 |
| 52.253-1 | Computer Generated Forms | JAN 1991 |
| 252.203-7000 | Requirements Relating to Compensation of Former DoD Officials | SEP 2011 |
| 252.203-7001 | Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies | DEC 2008 |
| 252.203-7002 | Requirement to Inform Employees of Whistleblower Rights | SEP 2013 |
| 252.203-7003 | Agency Office of the Inspector General | AUG 2019 |
| 252.204-7000 | Disclosure Of Information | OCT 2016 |
| 252.204-7003 | Control Of Government Personnel Work Product | APR 1992 |
| 252.204-7012 | Safeguarding Covered Defense Information and Cyber Incident Reporting | DEC 2019 |
| 252.204-7015 | Notice of Authorized Disclosure of Information for Litigation Support | MAY 2016 |
| 252.204-7018 | Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services | DEC 2019 |
| 252.209-7004 | Subcontracting With Firms That Are Owned or Controlled By The Government of a Country that is a State Sponsor of Terrorism | MAY 2019 |
| 252.211-7007 | Reporting of Government-Furnished Property | AUG 2012 |
| 252.222-7006 | Restrictions on the Use of Mandatory Arbitration Agreements | DEC 2010 |
| 252.223-7004 | Drug Free Work Force | SEP 1988 |
| 252.225-7001 | Buy American And Balance Of Payments Program-- Basic | DEC 2017 |
| 252.225-7002 | Qualifying Country Sources As Subcontractors | DEC 2017 |
| 252.225-7012 | Preference For Certain Domestic Commodities | DEC 2017 |
| 252.225-7048 | Export-Controlled Items | JUN 2013 |
| 252.227-7000 | Non-estoppel | OCT 1966 |
| 252.227-7001 | Release Of Past Infringement | SEP 2019 |
| 252.227-7015 | Technical Data--Commercial Items | FEB 2014 |
| 252.227-7018 | Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program | FEB 2014 |
| 252.227-7025 | Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends | MAY 2013 |
| 252.227-7030 | Technical Data--Withholding Of Payment | MAR 2000 |
| 252.227-7037 | Validation of Restrictive Markings on Technical Data | SEP 2016 |
| 252.231-7000 | Supplemental Cost Principles | DEC 1991 |
| 252.232-7010 | Levies on Contract Payments | DEC 2006 |
| 252.235-7002 | Animal Welfare | DEC 2014 |
| 252.235-7004 | Protection of Human Subjects | JUL 2009 |
| 252.242-7006 | Accounting System Administration | FEB 2012 |
| 252.243-7001 | Pricing Of Contract Modifications | DEC 1991 |
| 252.243-7002 | Requests for Equitable Adjustment | DEC 2012 |
| 252.244-7000 | Subcontracts for Commercial Items | JUN 2013 |
| 252.244-7001 | Contractor Purchasing System Administration | MAY 2014 |
| 252.245-7001 | Tagging, Labeling, and Marking of Government-Furnished Property | APR 2012 |
| 252.245-7002 (Dev) | Reporting Loss of Government Property (DEVIATION 2020-O0004) | FEB 2020 |
| 252.245-7003 | Contractor Property Management System Administration | APR 2012 |
| 252.245-7004 | Reporting, Reutilization, and Disposal | DEC 2017 |
| 252.247-7023 | Transportation of Supplies by Sea | FEB 2019 |

CLAUSES INCORPORATED BY FULL TEXT

52.204-1 APPROVAL OF CONTRACT (DEC 1989)

This contract is subject to the written approval of the Contracting Officer and shall not be binding until so approved.

(End of clause)

52.216-7 ALLOWABLE COST AND PAYMENT (AUG 2018)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor categories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242-4,
Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General organizational information and limitation on allowability of compensation for certain contractor personnel. See 31.205-6(p). Additional salary reference information is available at https://www.whitehouse.gov/wp-content/uploads/2017/11/ContractorCompensationCapContractsAwardedBeforeJune24.pdf and https://www.whitehouse.gov/wp-content/uploads/2017/11/ContractorCompensationCapContractsAwardedafterJune24.pdf.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(5) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.216-8 FIXED FEE (JUN 2011)

(a) The Government shall pay the Contractor for performing this contract the fixed fee specified in the Schedule.

(b) Payment of the fixed fee shall be made as specified in the Schedule; provided that the Contracting Officer withholds a reserve not to exceed 15 percent of the total fixed fee or $100,000, whichever is less, to protect the Government's interest. The Contracting Officer shall release 75 percent of all fee withholds under this contract after receipt of an adequate certified final indirect cost rate proposal covering the year of physical completion of this contract, provided the Contractor has satisfied all other contract terms and conditions, including the submission of

the final patent and royalty reports, and is not delinquent in submitting final vouchers on prior years' settlements. The Contracting Officer may release up to 90 percent of the fee withholds under this contract based on the Contractor's past performance related to the submission and settlement of final indirect cost rate proposals.

(End of clause)

52.227-11 PATENT RIGHTS--OWNERSHIP BY THE CONTRACTOR (MAY 2014)

(a) As used in this clause--

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made.

It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, “This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention.”

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. N/A

(k) Subcontracts. (1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes statute in connection with proceedings under paragraph (h) of this clause.

(End of clause)

52.244-2 SUBCONTRACTS (OCT 2010)

(a) Definitions. As used in this clause--

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

N/A

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining
the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

Subcontractors: (b) (4) [redacted]

Consultants: (b) (4) [redacted]
(b) (4) [redacted]

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more 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 at this/these address(es):

https://www.acquisition.gov/content/regulations

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any DoD Federal Acquisition Regulation Supplement (DFARS) (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.201-7000 CONTRACTING OFFICER'S REPRESENTATIVE (DEC 1991)

(a) "Definition. Contracting officer's representative" means an individual designated in accordance with subsection 201.602-2 of the Defense Federal Acquisition Regulation Supplement and authorized in writing by the contracting officer to perform specific technical or administrative functions.

(b) If the Contracting Officer designates a contracting officer's representative (COR), the Contractor will receive a copy of the written designation. It will specify the extent of the COR's authority to act on behalf of the contracting officer. The COR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

(End of clause)

252.227-7039 PATENTS--REPORTING OF SUBJECT INVENTIONS (APR. 1990)

The Contractor shall furnish the Contracting Officer the following:

(a) Interim reports every twelve (12) months (or such longer period as may be specified by the Contracting Officer) from the date of the contract, listing subject inventions during that period and stating that all subject inventions have been disclosed or that there are no such inventions.

(b) A final report, within three (3) months after completion of the contracted work, listing all subject inventions or stating that there were no such inventions.

(c) Upon request, the filing date, serial number and title, a copy of the patent application and patent number, and issue data for any subject invention for which the Contractor has retained title.

(d) Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(End of clause)

252.235-7010 Acknowledgment of Support and Disclaimer. (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the U.S. Army Medical Research and Development Command (USAMRDC)/U.S. Army Medical Materiel Development Activity (USAMMDA) under Contract No. W81XWH20C0066.

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the USAMRDC/USAMMDA or U.S. Army Medical Research Acquisition Activity (USAMRAA).

(End of clause)

252.235-7011 FINAL SCIENTIFIC OR TECHNICAL REPORT (DEC 2019)

The Contractor shall--

(a) Submit an electronic copy of the approved final scientific or technical report, not a summary, delivered under this contract to the Defense Technical Information Center (DTIC) through the web-based input system at https://discover.dtic.mil/submit-documents/ as required by DoD Instruction 3200.12, DoD Scientific and Technical Information
Program (STIP). Include a completed Standard Form (SF) 298, Report Documentation Page, in the document, or complete the web-based SF 298.

(b) For instructions on submitting multi-media reports, follow the instructions https://discover.dtic.mil/submit-documents/.

(c) Email classified reports (up to Secret) to dtic.belvoir.da mbx.tr@mail.smil mil. If a SIPRNET email capability is not available, follow the classified submission instructions at https://discover.dtic.mil/submit-documents/.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

| DOCUMENT TYPE | DESCRIPTION | PAGES | DATE |
|---|---|---|---|
| Exhibit A | CDRL Data Item A002- Regulatory Strategy/Development Plan | 1 | 01-MAY-2020 |
| Exhibit A | CDRL Data Item A003 - cGMP Manufacturing Documentation | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A005 - Pre-Clinical Data | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A001 - Quality Management Plan | 1 | 01-MAY-2020 |
| Exhibit A | CDRL Data Item A004 - FDA Interactions | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A006 - Clinical Trial Data | 1 | 01-MAY-2020 |
| Exhibit B | CDRL Data Item B001 - Final Technical Report | 1 | 28-APR-2020 |
| Attachment 1 | Scope of Work | 15 | 26-MAY-2020 |
| Attachment 2 | Quality Assurance Surveillance Plan (QASP) | 8 | 03-JUN-2020 |
| Attachment 3 | DFARS 252.227-7017 Assertions | 4 | 16-JUN-2020 |

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
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| U | 1 \| 3 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00001 | 24-Jun-2020 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| USA MED RESEARCH ACQ ACTIVITY<br>820 CHANDLER ST<br>FORT DETRICK MD 21702-5014 | W81XWH | See Item 6 | |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| OPH REX, NC.<br>(b) (6) [redacted]<br>5643 PARADISE DR #2<br>CORTE MADERA CA 94925-1815 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W81XWH20C0066 |
| | X | 10B. DATED (SEE ITEM 13)<br>19-Jun-2020 |
| CODE 7JTR0 | FACILITY CODE 7JTR0 | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☒ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

## 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: dblackst203521

a. The purpose of this administrative modification is to re-attach Exhibit A-A002 and Attachment 2 within the contract writing system in order for it to properly upload into the Electronic Document Access (EDA) system.

b. An error in the naming convention used when Exhibit A-A002 and Attachment 2 were attached to the award within the contract writing system caused the inability to upload the documents into the EDA system. As a result, the description in Section J for these two documents is changed to reflect the correct naming convention. There is no change to the Exhibit or Attachment, just the description in Section J.

c. This is a no cost modifcation. The contract funding and value remain the same at $9,873,778.00.

d. All other terms and conditions of this award remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| | MICAELA BOWERS / CONTRACTING OFFICER<br>TEL: (301) 619-21173 EMAIL: Micaela.l.Bowers.civ@mail.mil |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. | 16C. DATE SIGNED |
|---|---|---|---|
| _____<br>(Signature of person authorized to sign) | | BY (b) (6) [redacted]<br>(Signature of Contracting Officer) | 24-Jun-2020 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The Table of Contents has changed from:

Exhibit/Attachment Table of Contents

| DOCUMENT TYPE | DESCRIPTION | PAGES | DATE |
|---|---|---|---|
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| Exhibit A | CDRL Data Item A003 - cGMP Manufacturing Documentation | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A005 - Pre-Clinical Data | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A001 - Quality Management Plan | 1 | 01-MAY-2020 |
| Exhibit A | CDRL Data Item A004 - FDA Interactions | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A006 - Clinical Trial Data | 1 | 01-MAY-2020 |
| Exhibit B | CDRL Data Item B001 - Final Technical Report | 1 | 28-APR-2020 |
| Attachment 1 | Scope of Work | 15 | 26-MAY-2020 |
| Attachment 2 | Quality Assurance Surveillance Plan (QASP) | 8 | 03-JUN-2020 |
| Attachment 3 | DFARS 252.227-7017 Assertions | 4 | 16-JUN-2020 |

to:

Exhibit/Attachment Table of Contents

| DOCUMENT TYPE | DESCRIPTION | PAGES | DATE |
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| Exhibit A | CDRL Data Item A003 - cGMP Manufacturing Documentation | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A002- Regulatory Strategy Development Plan | 1 | 01-MAY-2020 |
| Exhibit A | CDRL Data Item A005 - Pre-Clinical Data | 1 | 28-APR-2020 |
| Exhibit A | CDRL Data Item A006 - Clinical Trial Data | 1 | 01-MAY-2020 |

| | | | |
|---|---|---|---|
| Exhibit A | CDRL Data Item A001 - Quality Management Plan | 1 | 01-MAY-2020 |
| Exhibit B | CDRL Data Item B001 - Final Technical Report | 1 | 28-APR-2020 |
| Attachment 1 | Scope of Work | 15 | 26-MAY-2020 |
| Attachment 2 | Quality Assurance Surveillance Plan | 8 | 03-JUN-2020 |
| Attachment 3 | DFARS 252.227-7017 Assertions | 4 | 16-JUN-2020 |

(End of Summary of Changes)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
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| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00002 | 04-Aug-2020 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| USA MED RESEARCH ACQ ACTIVITY<br>820 CHANDLER ST<br>FORT DETRICK MD 21702-5014 | W81XWH | See Item 6 | |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| OPH REX, NC.<br>(b) (6)<br>5643 PARADISE DR #2<br>CORTE MADERA CA 94925-1815 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W81XWH20C0066 |
| | X | 10B. DATED (SEE ITEM 13)<br>19-Jun-2020 |
| CODE 7JTR0 | FACILITY CODE 7JTR0 | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☒ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

## 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: dblackst204185

a. The purpose of this administrative modification is to correct the period of performance, Ship To Address and DoDAAC associated with Contract Line Identification Number (CLIN) 0004.

b. The period of performance, Ship To Address and DoDAAC associated with CLIN 0004 were erroneously missed at the time of contract award. The period of performance, Ship To Address and DoDAAC for CLIN 0004 are the same as all of the CLINs identified in Sections B and F and are hereby changed from N/A to Delivery Date - 19 June 2020 through 18 June 2023; Ship To Address - USA MED MATERIEL DEV ACTIVITY, USAMMDA, 1430 VETERANS DRIVE, FORT DETRICK MD 21702-9232 3016197860; and DoDAAC - W806YH.

c. This is a no-cost modification. The contract funding and value remain the same at $9,873,778.00.

d. All other terms and conditions of this contract remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| | TEELY EVA SHAFFER / CONTRACTING OFFICER<br>TEL: 301-619-2063 EMAIL: teelye.shaffer.civ@mail.mil |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. (b) (6) | 16C. DATE SIGNED |
|---|---|---|---|
| (Signature of person authorized to sign) | | (Signature of Contracting Officer) | 03-Aug-2020 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0004 has been added:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| POP 19-JUN-2020 TO 18-JUN-2023 | N/A | USA MED MATERIEL DEV ACTIVITY<br>USAMMDA<br>1430 VETERANS DRIVE<br>FORT DETRICK MD 21702-9232<br>(b) (6)<br>FOB: Destination | W806YH |

(End of Summary of Changes)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| U | 1 17 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00003 | 04-Dec-2020 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| USA MED RESEARCH ACQ ACTIVITY<br>820 CHANDLER ST<br>FORT DETRICK MD 21702-5014 | W81XWH | See Item 6 | |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| OPH REX, NC.<br>(b) (6)<br>5643 PARADISE DR #2<br>CORTE MADERA CA 94925-1815 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W81XWH20C0066 |
| | X | 10B. DATED (SEE ITEM 13)<br>19-Jun-2020 |
| CODE 7JTR0 | FACILITY CODE 7JTR0 | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

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☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
FAR 52.243-1 (Alt V)

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 2 copies to the issuing office.

## 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: dblackst21923

a. The purpose of this modification is to bring the contract into compliance with National Defense Authorization Act (NDAA) Section 889(a)(1)(B), revise reporting submission, and make administrative changes to the award.

b. Pursuant to NDAA Section 889(a)(1)(B) FAR Provisions 52.204-24 and 52.204-26 are incorporated by reference in Section I.

c. Contractor Manpower Reporting contained in Section B, CLIN 0007 and Section C, Statement of Work, paragraph C12.1 are removed and reflected as RESERVED.

d. Per the request made by Ophirex on 15 September 2020 and approved by the Contracting Officer's Representative 23 September 2020, the Invoice and Spend Plan requirements are revised in the Deliverables Table, paragraph C12, to reflect submission "NLT 15th of each month".

e. This is a no cost modification. The funding and contract value remain the same at $9,873,778.00.

f. All other terms and conditions of this contract remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| | TEELY EVA SHAFFER / CONTRACTING OFFICER<br>TEL: 301-619-2063 EMAIL: teelye.shaffer.civ@mail.mil |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. BY (b) (6) | 16C. DATE SIGNED |
|---|---|---|---|
| (Signature of person authorized to sign) | | (Signature of Contracting Officer) | 03-Dec-2020 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0007
The CLIN description has changed from Contractor Manpower Reporting (CMR) to RESERVED.
The CLIN extended description has changed from:

Provide information for the duration of Phase III performance associated with the input of the Accounting for Contract Services information in the website operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. UIC: W4QFAA; PSC: AN94

To:

.

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:
STATEMENT OF WORK:

C1. Background:

C1.1 Small Business Innovation Research (SBIR) Program:

C1.1.1. SBIR Program Background: The US Army Medical Research and Development Command, in support of the Department of Defense Small Business Innovation Research (SBIR), has taken part in the Defense Health Agency (DHA) Program Broad Agency Announcement (BAA) for FY 2018.1. Objectives of the solicitation included stimulating technological innovation in the private sector, strengthening the role of the small business in meeting Federal research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, increasing the commercial application of DOD-supported research results, and improving their return on investment from Federally-funded research for economic and social benefits to the Nation. The Federal SBIR Program is mandated by Public Laws 97-219, 99-443, 102-564 (STTR) and 106-554.

C1.1.2 SBIR Phased Program:

C1.1.2.1. Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR program. The contractor shall concentrate on that research or development which will significantly contribute to providing the scientific or technical feasibility of the approach or concept and which would be a prerequisite to further DOD support in Phase II.

C1.1.2.2. Phase II awards are made to firms with approaches that appear sufficiently promising as a result of Phase I. Phase II awards typically cover 2-5 man-years of effort and to cover a period generally not to exceed 24 months,

subject to negotiation. The number of Phase II awards will depend upon Phase I results and availability of funds. Phase II is the principal research or development effort; it will require a more comprehensive proposal, outlining the proposed effort, as explained below. Agencies may offer special SBIR awards, such as Phase II Enhancement awards, that supplement or extend Phase II awards. The Phase II Enhancement awards differ from base Phase II in that they require third party matching of the SBIR funds. Each such supplemental award must be linked to a base Phase II award.

C1.1.2.3. Under Phase III, it is intended that non-Federal capital be used by the small business to pursue commercial applications of the research or development. Also, under Phase III, Federal agencies may award non-SBIR funded follow-on contracts for products or processes, which meet the mission needs of those agencies.

C2. Targeting sPLA2 for Treatment of Acute Respiratory Distress syndrome Associated with SARs-CoV-2:

C2.1. Acute respiratory distress syndrome (ARDS) is associated with physical, physiological and infectious insults such as those caused by blunt trauma, barotrauma and, most currently and urgently of interest, pandemic SARS-CoV-2 infections. Mortality in patients with SARS-CoV-2 infection that develops into ARDS is extremely high even with optimal therapy, and long-term morbidity is severe. Coronaviruses in the SARS group (e.g. SAR-CoV-1, -2 and MERS) have mortality rates linked to ARDS approach 50% in patients with co-morbidities. Ophirex seeks to conduct clinical studies of treatment with Varespladib to reduce progression to and severity of COVID-19 associated ARDS. COVID-19 mortality rates are strongly linked to ARDS which, in turn, is also strongly correlated with phospholipase A2 (sPLA2) elevation. SPLA2 is a critical mediator of normal inflammatory response associated with infection, but systemic overexpression of sPLA2 feeds into cytokine overexpression and Cytokine Release Syndrome [AKA Systemic Inflammatory Response Syndrome (SIRS) or "cytokine storm"], which frequently results in ARDS. Critically, elevations in sPLA2 result in enzymatic degradation of surfactant and even greater release of factors, including TNF-a, TNF-B and IL-6. These cycles of inflammation and surfactant destruction act synergistically to the point at which the innate immune response to insult becomes lethally maladaptive. Uniquely, inhibition of sPLA2 can restore immune homeostasis and enhance respiratory function via prevention of reversal of cytokine storm and direct protection of surfactant from enzymatic degradation.

C2.3. The U.S. Army Medical Materiel Development Activity (USAMMDA) Warfighter Protection and Acute Care Project Management Office (WPAC PMO) seeks to utilize an innovative and experienced biopharmaceutical company to advance development and achieve FDA licensure of an inhibitor of SAR-CoV-2-related ARDS that is easy to use and shelf-stable that will protect the Force (population 18-55 years of age).

C3. Objectives:

To conduct the primary focus of this work, Ophirex will support a clinical study to determine the safety and efficacy of Varespladib to control or prevent COVID-19 associated ARDs as an addition to standard of care. Additional work to support this primary focus includes cGMP manufacturing of drug products, non-clinical validation of Varespladib efficacy, and regulatory and product development strategy through Investigational New Drug (IND) approval. Final expected timelines proposed in the Integrated Master Schedule will depend on pandemic patient load, clinical outcome and regulatory environment.

C3.1. Technical Objectives:

C3.1.1. Manufacturing of cGMP drug product of quantity and quality that is suitable and appropriate for use in clinical studies to demonstrate safety and efficacy against SARS-CoV-2 associated ARDS in humans.

C3.1.1.1. Manufacturing with stability of Oral Solid Dose (OSD) drug product batch

C3.1.1.1.1. Oral solid dose stability

C3.1.1.2. Manufacturing with stability of sterile injectable IV lyophilized drug product batch

C3.1.1.2.1. Lyophilized sterile IV product Stability

C3.1.1.3. Reduction of reliance on just in time manufacturing for Key Raw Materials of LY333013 and LY315920

C3.1.2. Non-clinical validation of sPLA2 as a therapeutic target and efficacy of Varespladib to reduce lung tissue inflammation, spare surfactant, and reduce ARDS

C3.1.2.1. Validation of Varespladib efficacy in animal model of coronavirus infection

C3.1.3. Advancement of Regulatory and Product Development strategy through filing and approval of IND application

C3.1.3.1. Quality Program support for GMP, GLP and GCP

C3.1.3.2. Develop Regulatory and Product Development Strategy for SARS-CoV-2 application

C3.1.3.3. Regulatory Filings up to and including an approved IND

C3.1.4. Clinical study in patients with suspected or confirmed SARS-CoV-2 to determine safety and efficacy of Varespladib to reduce incidence and severity of ARDS in conjunction with SOC

C3.1.4.1. Develop Clinical Strategy & Product Development

C3.1.4.2. Human Research Protection Office (HRPO) and Institutional Review Board (IRB) reviews

C3.1.4.3. Conduct Clinical Study

C3.2. Management Objectives:

C3.2.1. Management of Ophirex Integrated Product Development Team, including core and sub-teams supporting Non-Clinical, Clinical, CMC, Quality, and Commercialization work.

C3.2.2. Program management of both the primary contractual requirements supporting this SBIR III proposal as well as maintenance of distinct work streams between SARS-CoV-2 SBIR III and separate Broad-Spectrum snakebite antidote SBIR III proposed work.

C4. Scope of Work:

C4.1. Research Title: "Targeting sPLA2 for Treatment of ARDS Associated with SARs-CoV-2"

C4.2. The contractor shall, for the research period of 32 months plus an additional 120 days are provided for the submission of the final technical report following contract award, furnish the necessary personnel, facilities, equipment, and supplies to conduct Phase III of the study cited above. The Statement of Work, as contained in the Contractor's Technical Proposal dated 26 May 2020 in response to the DHA SBIR Broad Agency Announcement (BAA) No. 2018.1, Topic DHA18-002, is incorporated into this award. The contractor shall perform the following concurrent tasks to meet the objectives laid out in section C3 with detailed description outlined in Attachment 1:

C4.2.1. Technical Objective 1:

C4.2.1.1. Task 1.A. Manufacturing with stability of Oral Solid Dose (LY333013) Drug Product

C4.2.1.1.1. Subtask 1.A.1 Oral Solid Dose Stability

C4.2.1.1.2. Task 1.A. Milestones and Deliverables

C4.2.1.2. Task 1.B. Manufacturing with stability of sterile, injectable lyophilized Varespladib drug product (LY315920)

C4.2.1.2.1. Subtask 1.A.2 Lyophilized Sterile IV Product Stability

C4.2.1.2.2. Milestones and Deliverables

C4.2.1.3. Task 1.C. Reduction of reliance on just in time manufacturing for Key Raw Materials of LY333013 and LY315920

C4.2.1.3.1. Milestones and Deliverables

C4.2.2. Technical Objective 2:

C4.2.2.1. Task 2.A. Validation of efficacy in an animal model of coronavirus

C4.2.2.2. Milestones and Deliverables

C4.2.3. Technical Objective 3:

C4.2.3.1. Task 3.A. Quality Program support for GMP, GLP and CGP

C4.2.3.1.1. Milestones and Deliverables

C4.2.3.2. Task 3.B. Development of Regulatory and Product Development Strategy for Varespladib as Therapeutic for SARS-CoV-2 Associated ARDS

C4.2.3.2.1. Milestones and Deliverables

C4.2.3.3. Task 3.C. Regulatory Filings Up to and Including IND

C4.2.3.3.1. Milestones and Deliverables

C4.2.4. Technical Objective 4:

C4.2.4.1. Task 4.A. Clinical Strategy and Protocol Development

C4.2.4.1.1. Milestones and Deliverables

C4.2.4.2. Task 4.B. Human Research Protection Office (HRPO) and Institutional Review Board (IRB) Approval

C4.2.4.2.1. Milestones and Deliverables

C4.2.4.3. Task 4.C. Clinical Study

C4.2.4.3.1. Milestones and Deliverables

C4.2.5. Management Objectives:

C4.2.5.1. Integrated Product Development Team (IPT) Management

C4.2.5.2. Contract Management

C4.2.5.2.1. Milestones and Deliverables

C5. PLACE OF PERFORMANCE

C5.1. Place of performance includes the following locations:

C5.1.1. Prime: Ophirex, Inc., 5643 Paradise Drive, #2, Corte Madera, California, 94925

C5.1.2. Subcontractor: (b) (4)

C5.1.2.1. Subcontractor: (b) (4)

C5.1.2.2. Subcontractor: (b) (4)

C5.1.2.3. Subcontractor: (b) (4)

C5.1.2.4. Subcontractor: (b) (4)

C5.1.3. Subcontractor: (b) (4)

C5.1.4. Subcontractor: (b) (4)

C5.1.5. Subcontractor: (b) (4)

C5.1.6. Consultants: (b) (4)

C5.1.7. Consultants: (b) (4)

C6. Quality Assurance:

C6.1. Oversight of contractor performance shall be in compliance with the Quality Assurance Surveillance Plan (QASP), found at Attachment 2 to this contract.

C7. RESERVED

C8. Contractor Identification:

C8.1. When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

C8.2. While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications

C9. Key Personnel:

C9.1. The following positions have been identified to be filled by Key Personnel proposed for this award.

Position Title: Co-Principal Investigator/Chief Scientist/Chief Medical Officer
Co-Principal Investigator/Chief Development Officer

C9.2. The approved Personnel identified to fill the Key Personnel positions shall be utilized as necessary to fulfill the requirements of this contract.

C9.3. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or change in employment conditions (e.g. termination, change in position, etc.). In any of these events, the contractor shall promptly notify the Contracting Officer in writing and provide the information required by paragraph C7.4 below.

C9.4. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). Any proposed substitute or replacement key personnel shall have qualifications comparable to the individual being replaced, taking into account the requirements of the SOW. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

C9.5. If any of the listed Key Personnel are subcontractor personnel, the contractor shall flow down the substance of this instruction in any subcontract which is awarded in support of this contract.

C10. CO-PRINCIPAL INVESTIGATOR'S:

The Co-Principal Investigator's shall be continuously responsible for the conduct of the research project. The contractor shall obtain the Contracting Officer's approval to change one or both of the Co-Principal Investigator's or to continue the research work during a continuous period in excess of three months without the participation of both approved Co-Principal Investigator's. This contract is based on the Co-Principal Investigator's devoting the number of hours proposed in the approved budget to the project over the term of the contract. The contractor shall advise the Contracting Officer if the Co-Principal Investigator's will, or plans to, revise the level of effort estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

C11. General Requirements:

C11.1. PROHIBITION OF USE OF HUMAN SUBJECTS

C11.1.1. Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, shall not begin until the USAMRDC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRDC ORP, under separate notification to the contractor. Written approval from the USAMRDC ORP is also required for any subcontractor that will use funds from this contract to conduct research involving human subjects.

C11.1.2. Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRDC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRDC. Research records shall be stored in a confidential manner in accordance with FAR 52.224-2.

C11.1.3. The contractor is required to adhere to the following reporting requirements:

C11.1.4. Submission of substantive modifications to the protocol, continuing review documentation, and the final report as outlined in the USAMRDC ORP approval memorandum.

C11.1.5. Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the contractor, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRDC ORP.

C11.1.6. The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of

serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRDC ORP.

C11.1.7. Non-compliance with these terms and conditions may result in withholding of payments and/or the termination of the contract. The USAMRDC ORP Human Research Protection Office submission instructions can be accessed at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo**.**

C11.2. PROHIBITION OF USE OF HUMAN CADAVERS

C11.2.1. Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under this contract shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrdc.amedd.army mil/index.cfm/collaborate/research_protections/hrpo).

C11.2.2. The USAMRDC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other hrpo@mail.mil ) for this policy. Approval must be obtained from the USAMRDC ORP. Contractors must coordinate with the Contracting Officer Representative (COR) to ensure that proper approvals are obtained. ORP will issue written approvals to begin under separate notification to the contractor. Written approval to proceed from the USAMRDC ORP is also required for any subcontractor that will use funds from this award to conduct RDT&E, education or training involving human cadaveric specimens.

C11.2.3. Contractors must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the USAMRDC ORP. Contractors must maintain complete records of the activity.

C11.2.4. The USAMRDC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

C11.2.5. Non-compliance with these terms and conditions may result in withholding of payments and/or the termination of the contract.

C11.3. PROHIBITION OF USE OF LABORATORY ANIMALS

C11.3.1. Notwithstanding any other terms and conditions contained in this contract or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRDC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this contract will be issued in the form of an approval letter from the USAMRDC ACURO to the contractor. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, the contractor must maintain, and upon request from ACURO, submit animal usage information.

C11.3.2 Non-compliance with any of these terms and conditions may result in withholding of payment and/or the termination of the contract.

C11.3.3 The Animal Care and Use Office requirements can be accessed at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro.

C11.4. INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT:

C11.4.1. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

C11.4.2. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which US Army Medical Research and Development Command funds have been provided or requested.

C11.4.3. The contractor agrees to:

C11.4.3.1. Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;

C11.4.3.2. Comply with its own administrative process;

C11.4.3.3. Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;

C11.4.3.4. Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and

C11.4.3.5. Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

C11.4.4. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:

C11.4.4.1. An immediate health hazard is involved;

C11.4.4.2. There is an immediate need to protect Federal funds or equipment;

C11.4.4.3. A probability exists that the alleged incident will be reported publicly; or

C11.4.4.4. There is a reasonable indication of possible criminal violation.

C11.5. USE OF TECHNICAL REFERENCE FACILITY:

To the extent practical the Contractor shall utilize the technical reference facilities of the Defense Technical Information Center (DTIC) for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. The DTIC headquarters office is located at 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218. Information can also be obtained via the Internet at https://discover.dtic.mil or via the toll-free number for the DTIC help desk, 1-800-225-3842. To the extent practical, all other sources, whether or not Government controlled, should be consulted for the same purpose.

C11.6. FINANCIAL INSTABILITY, INSOLVENCY, BANKRUPTCY OR RECEIVERSHIP:

C11.6.1. Contractor will immediately notify the USAMRAA Contracting Officer of the occurrence of the following events:

C11.6.1.1. the contractor’s financial instability that would negatively impact performance of this contract;

C11.6.1.2. the contractor or contractor’s parent company's filing of a voluntary case seeking liquidation or reorganization under the Bankruptcy Act;

C11.6.1.3. the contractor’s consent to the institution of an involuntary case under the Bankruptcy Act against the contractor or contractor’s parent company;

C11.6.1.4. the filing of any similar proceeding for or against the contractor or contractor’s parent company, or its consent to, the dissolution, winding-up or readjustment of the contractor’s debts, appointment of a receiver,

conservator, trustee, or other officer with similar powers over the organization, under any other applicable state or federal law; or

C11.6.1.5. the recipient's insolvency due to its inability to pay its debts generally as they become due.

C11.6.2. Such notification shall be in writing and shall:

C11.6.2.1. specifically set out the details of the occurrence of an event referenced in paragraph a;

C11.6.2.2. provide the facts surrounding that event; and

C11.6.2.3. provide the impact such event will have on the research and development being funded by this contract.

C11.6.3. Upon the occurrence of any of the five events described in the first paragraph, the Government reserves the right to review contractor's performance to determine if there are significant deficiencies or concerns that would undermine the government's investment in Contractor's work. The Government reserves the right to impose additional requirements, as needed, including:

C11.6.3.1. change the payment method;

C11.6.3.2. institute payment controls, and

C11.6.3.3. require additional reporting requirements. In addition, should any of the five events described in the first paragraph occur, the Government may elect that Contractor transfer possession, ownership and sponsorship/ holdership of any Regulatory Application or intellectual property resulting from this contract in accordance with the procedure and conditions set forth in the clause entitled "Regulatory Rights of Product Development Failures (2012)" incorporated herein.

C11.6.4. Failure of the Contractor to comply with this term may be considered a grounds for the termination of this contract.

C11.7. REGULATORY RIGHTS IN EVENT OF PRODUCT DEVELOPMENT FAILURES

C11.7.1. This contract includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this contract will result in the submission of an investigational new drug application (IND) to the FDA, with subsequent approval of the IND, for a Treatment of Acute Respiratory Distress Syndrome (ARDS) Associated with SARS-CoV-2 or the "Technology." The Contractor is the sponsor of the IND that controls the research under this contract. As the sponsor of the IND (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the IND. This provision protects the return on research and development investment made by the Army Medical Research and Development Command (USAMRDC).

C11.7.2. (b) (4) [redacted]:

a. (b) (4) [redacted]

b. (b) (4) [redacted]:

(1) (b) (4) [redacted]

(2) (b) (4) [redacted].

(3) (b) (4) [redacted].

c. (b) (4) [redacted]

(1) (b) (4) [redacted]

(2) (b) (4) [redacted]

(3) (b) (4) [redacted];

(4) (b) (4) [redacted].

C11.7.3. The Contractor shall provide FDA submissions, communications, and interactions to USAMMDA as required in Contract Data Requirements List (CDRL), Exhibit A, Data Item A004, CLIN 0011, titled R&D of Medical Products Regulated by the U.S. FDA (DI-TCSP-82040).

C11.8. INDIRECT RATE CAP

In accordance with the Basis of Estimates dated 15 May 2020 and the Final Revised Cost Volume dated 8 June 2020, Opherix, Inc. has stated that (b) (4) [redacted]

C11.9. FOREIGN NATIONALS

C11.9.1 If Foreign Nationals are utilized, it is the company's responsibility to comply with all governing Federal International Traffic in Arms Regulations (ITAR) and applicable section(s) of the associated Broad Agency Announcement (BAA).

C12. Deliverables:

| No. | Deliverable | Distribution | Initial | Subsequent | Comments |
|---|---|---|---|---|---|
| 1 | IMS | COR | With Proposal | NLT 30 days after award | See Section 3 description for |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | updates to the IMS |
| 2 | CWBS | COR | With Proposal | NLT 30 days after award | Include updates in monthly report as needed |
| 3 | Team Meetings | N/A | Kick-off meeting at the time of contract award | As required, at least monthly | |
| 4 | CDRL-Exhibit A-A001<br>CLIN 0008<br>Quality Manufacturing Plan (QMP) | COR | NLT 45 days after award | N/A | Include updates in monthly report as needed |
| 5 | CDRL-Exhibit A-A002<br>CLIN 0009<br>Regulatory Strategy and Development Plan (RDP) | COR | NLT 45 days after award | N/A | Include updates in monthly report as needed |
| 6 | CDRL-Exhibit A-A003<br>CLIN 0010<br>cGMP Manufacturing Documentation | COR | Within 5 days of report generation or receipt | Deliver all subsequent documents within 5 days of generation or receipt | Include updates in monthly report as needed |
| 7 | CDRL-Exhibit A-A004<br>CLIN 0011<br>Regulatory documentation and FDA submissions | COR | At least 5 days prior to submission | Within 5 days of receipt from FDA | See description |
| 8 | CDRL-Exhibit A-A005<br>CLIN 0012<br>Non-clinical Study Documentation | COR | NLT 60 days after award | Upon ACURO approval (if required) and study completion | Include updates in monthly report as needed |
| 9 | Issue Summary Reports | COR | Within 5 days of breach identification | Report all subsequent breaches within 5 days of identification | |
| 10 | Monthly Technical Progress Reports | COR | NLT 45 days after award | NLT 15th of each month | |
| 11 | Spend Plan | COR | NLT 45 days after award | NLT 15th of each month | |
| 12 | CDRL-Exhibit A-A006<br>CLIN 0013<br>Clinical Study Documentation including Closeout Report | COR | NLT 45 days after award | Upon IRB approval, amendment approval, and study completion | Include updates in monthly report as needed |
| 13 | CDRL-Exhibit B-B001<br>CLIN 0014<br>Final Technical Report | COR, KO | Within 120 days following end of Phase III research period | N/A | Required by SBIR Policy |
| 14 | Patent/Invention Reporting DFARS 252.227-7039 | KO, iEdison | As outlined in the clause | As outlined in the clause | DFARS Requirement |

C12.1. RESERVED

C12.2. Technical Reporting Requirements:

C12.2.1. Monthly Technical Progress Reports

C12.2.1.1. The contractor shall submit a Monthly Technical Progress Report covering work accomplished during each month of contract performance. It shall be brief, factual, and informal, and shall be prepared in accordance with the following:

C12.2.1.1.1. Cover containing:

C12.2.1.1.1.1. Contract number and title

C12.2.1.1.1.2. Type of report, sequence number of report, and period of performance being reported

C12.2.1.1.1.3. Contractor's name, address, and telephone number

C12.2.1.1.1.4. Principal Investigator

C12.2.1.1.1.5. Date of publication

C12.2.1.1.1.6. Contracting Officer's Representative (COR)

C12.2.1.1.2. Section I – Introduction and Project Summary (Purpose and Scope of Research Effort). A brief introduction covering the purpose and scope of the research effort (one paragraph summary).

C12.2.1.1.3. Section II – Progress

C12.2.1.1.3.1. Overall Progress Summary. A brief description of overall progress to date for the reporting period (one-two paragraphs summary).

C12.2.1.1.3.2. Individual Task Progress. A separate description for each task or other logical segment of work on which effort was expended during the report period, briefly describing the work that has been performed. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. List all tasks associated with the approved Statement of Work (SOW) including those with no activity performed for the period and status stating as such (i.e. have not started, no work conducted this period, started, delayed, % completed, etc.).

C12.2.1.1.4. Section III - Problems and Changes

C12.2.1.1.4.1. Problems Encountered. A description of current problems that may impede performance, including impact on expenditures, along with proposed corrective action. Report any changes (e.g. staff addition/removal/FTE reduction/increase, approaches, etc.) that happened and why. Note some changes require Contracting Officer's review and expressed written approval through a formal award modification before implementation.

C12.2.1.1.4.2. Problems Anticipated. A description of anticipated problems that have a potential to impede progress and/or impact expenditures, and what corrective action is planned should the problem materialize. Report any changes (e.g. staff, approaches, etc.) planned and why. Note some changes require Contracting Officer's review and expressed written approval through a formal award modification before implementation.

C12.2.1.1.5. Section IV - Next Month Actions. A brief description of work to be performed during the next reporting period for each task. If no work is planned for a task then state so and why if appropriate.

C12.2.1.1.6. Section V - Administrative Comments - Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.

C12.2.1.1.7. Section VI – Research Protocols and Regulatory Status

C12.2.1.1.7.1. Protocol Status. List each protocol planned for the project including title, protocol identifiers (i.e. IACUC number, ACURO number, name of regulatory review board, etc.), type of animals, number of animals, protocol PI, protocol site, etc., and note status of each (e.g. in development, submitted to regulatory agency such as IACUC, ACURO, FDA for review, approval date with name of regulatory authority, date of continuing review or rewrite review, amendments with brief statement of the changes and its status such as submitted and/or approved by which regulatory authority, etc.)

C12.2.1.1.7.2. Adverse Events. Describe any adverse events and actions taken.

C12.2.1.1.8. Section VII - A Gantt Chart showing actual progress versus scheduled progress.

C12.2.1.2. Monthly Technical Progress Reports: The first monthly report will be due 40 days after the start date of the period of performance (10 days after completion of the first 30 days of performance) and then monthly thereafter.

C12.2.1.3. Monthly Technical Progress Reports and Invoice Submission. The Monthly Technical Progress Reports and Invoices shall be submitted electronically to https://ebrap.org for review prior to submission through Wide Area Workflow (WAWF) for Payment. The COR shall have five (5) calendar days to provide comment to the contractor. If the COR does not provide comment within 5 days of submission, the contractor may submit their invoice via WAWF.

C12.3. Deliverable 1 - Integrated Master Schedule. The contractor shall provide an Integrated Master Schedule (IMS) depicting all contract activities linked to the WBS level, as applicable. The IMS shall contain all critical and high- risk efforts identified by the contractor or Government to ensure these are realistically planned and executable. The IMS shall include activities of major subcontractors and suppliers, as applicable. All tasks/ activities in the IMS shall be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program under the agreement.

C12.3.1. The initial IMS shall be provided with the proposal. Provide an IMS update with the monthly status report only if changes in schedule have occurred or are anticipated to occur. Provide the IMS in PDF format indicating monthly task progress, percent completion, and schedule acceleration/slippage. The IMS shall include the approved baseline schedule and the actual schedule.

C12.3.2. Draft changes to the IMS, specifically program level 3 or above milestones or the critical path, shall be submitted to the government for approval. The government will respond with comments or approval 10 business days following receipt of draft changes. A final IMS with incorporated changes shall be submitted 5 business days after receipt of Government comment**s.**

C12.4. Deliverable 2 - Contract Work Breakdown Structure. The initial submission shall be provided with the proposal at a four-level WBS with costs and schedule (top level is program, level 2 is phase, level 3 are major tasks, level 4 are subordinate tasks). For lowest task level, show breakdown for labor, material, and other indirect costs.

C12.4.1. The Contract WBS (CWBS) shall be provided 30 days after award to the appropriate levels reflecting the deliverables for each task and updated annually or 30 calendar days after a SOW modification affecting the CWBS.

C12.4.2. The Government review/approval will be provided within 10 calendar days after receipt of each submittal. The contractor shall provide a final updated CWBS within 5 calendar days after receipt of Government comments/approval.

C12.5. Deliverable 3 - Team Meetings. The contractor shall engage in monthly teleconferences with the Government, beginning with the kick-off meeting at the time of contract award. The date and time of recurring meetings will be agreed upon by the Government and the contractor and ad hoc meetings shall be agreed upon as necessary. The Government will provide dial-in information and an agenda prior to the meeting; the contractor shall submit requests for specific agenda items three (3) days in advance of the meeting. The Government will record the meeting and provide meeting minutes to all participants.

C12.6. Deliverable 4 - Quality Management Plan. (CDRL Exhibit A-A001, DI-TCSP-82040) The contractor shall provide a QMP NLT 45 days after contract award and updates shall be included in the monthly progress reports. The QMP shall describe plans for the drug substance manufacturing process, process development, quality oversight, deviation reporting process, audits, cGMP compliance, and control/qualification/validation of all processes, facilities, equipment, raw materials, and assays. The QMP should include plans for tests required for human use to include: sterility, stability, and toxicology. Issues and questions from the QMP shall be discussed at the monthly teleconference.

C12.7. Deliverable 5 - Regulatory Strategy and Development Plan (RDP). (CDRL Exhibit A-A002, DI-TCSP-82040) The contractor shall provide a RDP NLT 45 days after contract award and updates shall be included in the monthly progress reports. The RDP shall describe the regulatory pathway, target product profile, and specific plans to meet regulatory objectives. The Plan shall include items listed by the cited DID Section 2a, 1-2 (Drugs and Biologics--Regulatory Strategy and RDP). Issues and questions from the Regulatory Strategy shall be discussed at the monthly teleconference and outlined in the monthly report.

C12.8. Deliverable 6 - GMP manufacturing documentation. (CDRL Exhibit A-A003, DI-TCSP-82040) Copies of the documentation of the cGMP manufacturing of the drug product shall be delivered to the Government within 5 days of receipt or generation by the Contractor. Documentation to be delivered shall include items listed in Section 2e (Drugs and Biologics -- Manufacturing) of the DID DI-TCSP-82040. Issues and questions from cGMP manufacturing or release for human use shall be discussed at the monthly teleconference and outlined in the monthly report.

C12.9. Deliverable 7 - Regulatory Documentation and FDA submissions. (CDRL Exhibit A-A004, DI-TCSP-82040) FDA submissions and communications include those items listed in the cited DID, Section 2b (Drugs and Biologics-FDA Interactions). This includes documentation regarding IND submission. For all Submission Packets, Contractor shall provide one draft copy and one final copy. For all other FDA Interactions, only a final copy is required. Items submitted to FDA by the Contractor shall be delivered to the Government at least 5 days prior to submission. Items received by the Contractor from the FDA shall be delivered to the Government within 5 days of receipt. Delivery schedule should be in agreement with the Integrated Master Schedule. Issues and questions from all FDA Interactions shall be discussed at the monthly teleconference and/or outlined in the monthly progress report.

C12.10. Deliverable 8 - Non-clinical Study Documentation. (CDRL Exhibit A-A005, DI-TCSP-82040) The Contractor shall submit a draft of the Experimental Design Plan/protocol within 60 business days after contract award in a format agreed upon by the contractor and the Government at the time of contract award. A final version shall be delivered at the time of experiment execution or IACUC submission (if required). If animal work is required, copies of IACUC and ACURO communication and decisions shall be delivered within 5 days of receipt by the Contractor. Progress, issues and questions from the pre-clinical tests and studies shall be discussed at the monthly teleconference and outlined in the monthly report. The final report of the study findings shall be delivered to the Government at the time of contract award.

C12.11. Deliverable 9 - Issue Summary Report(s): The Contractor shall provide details of any serious breach of plans (causing at least 3 month delay, 5% increase in cost or impaired performance attribute) as Issue Summary Report, as needed, within five (5) days of identifying the breach. The contractor shall report get-well plans and risk log updates to include risk mitigation strategies.

C12.12. Deliverable 10 - Monthly Technical Progress Reports. The contractor shall submit monthly

technical progress reports in accordance with the format included in the Deliverable Section, Paragraph C12.2.1, of the contract.

C12.13. Deliverable 11 - Spend Plan. The Contractor shall provide a Spend Plan which details how the Contractor expects to incur and invoice for costs against the contract. The Spend Plan shall detail costs to be incurred monthly by fiscal year (1 October - 30 September) and by contract year, starting with the first month of the contract period of performance. The Spend Plan total shall match with the total costs proposed for the entire task order in the Cost/Pricing Sheet. The Spend Plan shall be updated as necessary. The Contractor shall report actual progress against the Spend Plan in the Monthly Report.

C12.14. Deliverable 12 - Clinical Study Documentation (CDRL Exhibit A-A006, DI-TCSP-82040) The contractor shall provide a Clinical Study Plan, including the draft clinical protocol and related documents as listed in the cited DID Section 2d (Drugs and Biologics--Clinical Trials), within 45 days after the contract is awarded in a format agreed upon by the contractor and the Government at that time. The final version of the protocol shall be delivered at the time of IRB submission. Updates and amendments to the protocol shall be delivered within 5 days of submission. Copies of IRB and HRPO communication and decisions shall be delivered within 5 days of receipt by the contractor. Progress, issues and questions from the clinical trial shall be discussed at the monthly teleconference and outlined in the monthly report. The final clinical study report of the study findings shall be delivered to the Government upon completion of data analysis in a format agreed upon by the contractor and the Government at the time of contract award.

C12.15. Deliverable 13 - Final Technical Report (CDRL Exhibit B-B001, DI-MISC-80048) Final Technical Report shall be submitted within 120 calendar days after the "research ends" date for the Phase III effort. In accordance with DFARS clause 252.235-7011, the Final Technical Report shall be submitted to the Defense Technical Information Center (DTIC) upon the COR's approval of the report. The contractor shall provide to the Contract Specialist an electronic copy of DTIC's notification that the final report has been received.

C12.16. Deliverable 14 - Patent/Invention Reporting:

C12.16.1. SBIR/STTR awardees must report inventions to the component within two months of the inventor's report to the awardee. The reporting of inventions may be accomplished by submitting paper documentation, including fax, or through the Edison Invention Reporting System at www.iedison.gov.

C12.16.2. Closeout report. A final DD Form 882 is required, whether or not the contractor is reporting an invention. Submit the report within three months of end of the period of performance. List all inventions made during the period of performance or state "none," as applicable. The award will not be closed until the contractor has met all reporting requirements. Submit all DD Form 882 reports electronically to the Contract Specialist shown in Section A, Contract Summary.

C12.17. CONTRACTOR PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS)

C12.17.1. A CPARS assesses a contractor's performance and provides a record, both positive and negative, on a given contractor during a specific period of time. Each assessment is based on objective facts and supported by program and contract management data, such as cost performance reports, customer comments, quality reviews, technical interchange meetings, financial solvency assessments, construction/production management reviews, contractor operations reviews, functional performance evaluations, and earned contract incentives. Performance evaluations are transmitted into the Past Performance Information Retrieval System (PPIRS) which is used by government agencies to assess contractor past performance for future acquisitions. The contractor shall appoint a Contractor Representative (CR) and provide this information to the Contracting Officer (KO) within 10 calendar days of award. The contractor POC shall have the authority to comment on the CPAR assessment on behalf of their company and within the timeframes established.

C12.17.2. A CPARS assessment must be completed within 120 calendar days after the evaluation. Evaluations are sent to PPIRS within 14 calendar days after the government Assessing Official (AO) has submitted the rating. If the CR has not concurred/non- concurred with the rating; PPIRS will show the government evaluation as "Contractor

Comment Pending Review". The CR has a total of 60 calendar days to concur/non- concur with the assessment. After 60 days, the CR can either concur/non-cur. The CR has the authority to: access the Government evaluation; review/comment/concur or non-concur with the assessment within 60 calendar days after notification of the government's assessment. The CR has the right to request a meeting (in writing) with the government within 7 calendar days of notification of an assessment. Once the government and the CR complete the evaluation; an automatic update will be sent to PPIRS and visible for Source Selection. If the CR fails to respond within 60 days, the assessment will be finalized. Training for CPARS can be found on the CPARS website: https://www.cpars.gov/index.htm.

C12.17.3. To access CPARS, the contractor must have a Public Key Infrastructure (PKI). It is suggested an ECA certificate of Medium Assurance should be purchased. This should be a Department of Defense identity certificate, not an e-mail certificate.

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

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| 52.204-24 | Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment. | OCT 2020 |
| 52.204-26 | Covered Telecommunications Equipment or Services--Representation. | OCT 2020 |

(End of Summary of Changes)