UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 10, 2021

ContraFect Corporation
(Exact name of registrant as specified in its charter)

Delaware	001-36577	39-2072586
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

28 Wells Avenue, 3rd Floor, Yonkers, New York 10701
(Address of principal executive offices) (Zip Code)

(914) 207-2300
Registrant's telephone number, including area code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**CFRX**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On March 10, 2021, ContraFect Corporation (the "Company") entered into a cost-share contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, the Company will receive funding of up to an estimated $86.8 million to advance the development of the Company's product candidate, exebacase (CF-301), as a new anti-staphylococcal treatment modality (direct lytic agent).

The base period for the BARDA Contract includes government funding of up to $9.8 million to reimburse expenses for approximately one year to support the conduct of the ongoing Phase 3 clinical trial and futility analysis. Following successful completion of the base period, the BARDA Contract provides for approximately $77.0 million of additional BARDA funding for five options in support of the completion of the Phase 3 clinical trial of exebacase, further clinical and non-clinical studies, manufacturing, supply chain, clinical, regulatory and administrative activities. Under the BARDA Contract, the Company will be responsible for its cost share of up to an estimated $84.1 million if all development options are completed. The contract period-of-performance (base period plus option exercises) is up to approximately six years.

The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The foregoing description of the BARDA Contract does not purport to be complete and is qualified in its entirety by reference to the full text of the BARDA Contract, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

The Company issued a press release on March 11, 2021 announcing the BARDA Contract. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this report (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
10.1	Cost-Sharing Agreement by and between ContraFect Corporation and the BioMedical Advanced Research and Development Authority, dated March 10, 2021.
99.1	Press release of ContraFect Corporation, dated March 11, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CONTRAFECT CORPORATION

Date: March 12, 2021

By: /s/ Natalie Bogdanos
Natalie Bogdanos
General Counsel and Corporate Secretary

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(B)(10). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) u	RATING	PAGE 1	OF PAGES 72
2. CONTRACT *(Proc. Inst. Ident.)* NO. 75A50121C00021	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS272855		

5. ISSUED BY	CODE ASPR-BARDA	6. ADMINISTERED BY *(If other than Item 5)*	CODE
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201			SD-C

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*	8. DELIVERY ☐ FOB ORIGIN ☒ OTHER *(See below)* 9. DISCOUNT FOR PROMPT PAYMENT	
CONTRAFECT CORPORATION 1576315 Attn: MICHAEL MESSINGER CONTRAFECT CORPORATION 28 WELL 28 WELLS AVE FL 3 YONKERS NY 107017045	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN u	ITEM
CODE 1576315 FACILITY CODE		

11. SHIP TO/MARK FOR	CODE HHS/OS/ASPR	12. PAYMENT WILL BE MADE BY	CODE ASPR-BARDA
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201		ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVEL 200 INDEPENDENCE AVE, S.W; ROOM 640 Washington DC 20201	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a) ( )	2021.1992021.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15d. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
				15G. TOTAL AMOUNT OF CONTRACT u	$9,767,226.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE			
X	A	SOLICITATION/CONTRACT FORM	**PAGE 1**
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	**PAGE 4**
X	C	DESCRIPTION/SPECS./WORK STATEMENT	**PAGE 14**
X	D	PACKAGING AND MARKING	**PAGE 17**
X	E	INSPECTION AND ACCEPTANCE	**PAGE 18**
X	F	DELIVERIES OR PERFORMANCE	**PAGE 20**
X	G	CONTRACT ADMINISTRATION DATA	**PAGE 38**
X	H	SPECIAL CONTRACT REQUIREMENTS	**PAGE 45**

(X)	SEC.	DESCRIPTION	PAGE(S)
PART II - CONTRACT CLAUSES			
X	I	CONTRACT CLAUSES	**PAGE 63**
PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	J	LIST OF ATTACHMENTS	**PAGE 72**
PART IV - REPRESENTATIONS AND INSTRUCTIONS			
	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	M	EVALUATION FACTORS FOR AWARD	

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

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return _____ 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 items 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
Roger J. Pomerantz, M.D., President, CEO & Chairman	JAMES P. BOWERS

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
CONTRAFECT CORPORATION 1576315 BY /s/ Roger J. Pomerantz *(Signature of person authorized to sign)*	3/9/21	BY /s/ James P. Bowers *(Signature of the Contracting Officer)*	3/10/21

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

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

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50121C00021	PAGE OF 2 | 72

NAME OF OFFEROR OR CONTRACTOR
CONTRAFECT CORPORATION 1576315

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 39-2072586 DUNS Number: [***] Delivery: 02/20/2021 Appr. Yr.: 2021 CAN: [***] Object Class: [***] FOB: Destination Period of Performance: 02/18/2021 to 02/15/2022				
1	ASPR-21-00731 ContraFect – A Direct Lytic Agent to Combat Antimicrobial Resistance and Improve Clinical Cure Rates for Staphylococcus aureus (MRSA) Bacteremia Obligated Amount: $9,767,226.00				

CONTRACT TABLE OF CONTENTS

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) and was reauthorized under the PAHPA of 2013 and again in 2019 under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), Public Law No. 116-22, to support development and acquisition of medical countermeasure (MCMs) to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

ContraFect Corporation (referred to as "ContraFect") is developing exebacase (EXE; CF-301), a protein based direct lytic agent (DLA) which is the first member of a new class of antibacterials called lysins. Exebacase is a GMP-manufactured, purified, recombinant protein therapeutic with a novel mechanism of action (MOA) against antibiotic resistant *S. aureus* bacteremia (SAB), a serious, life-threating and chronically neglected disease for which the few currently available antibiotic treatment options are suboptimal. The microbiologic attributes and MOA of exebacase strongly differentiate it from traditional antibiotics. These defining properties of exebacase as well as its synergy with conventional antibiotics underpin the use of clinical studies designed to show superiority of exebacase in combination with standard of care relative to standard of care alone. Exebacase has been evaluated in Phase 1 and 2 clinical studies and granted Fast Track designation in 2015 and Breakthrough Therapy designation in 2020 by the Food and Drug Administration (FDA). The U.S. government is interested in exebacase due to its potential to meet an unmet medical need including the need for innovative antibiotics to treat secondary bacterial infections that complicate the U.S. government's (USG's) response to public health emergencies such as the COVID-19 pandemic.

The objective of this cost-share contract is to advance the development of exebacase (CF-301) as a new anti-staphylococcal treatment modality (direct lytic agent). Exebacase will be developed to be used in addition to standard of care antibiotics to combat methicillin-resistant *S. aureus* (MRSA) and improve clinical response rates for *S. aureus* bacteremia and right-sided infective endocarditis (R-IE). The base period-of-performance (CLIN 1) will comprise conduct of a Phase 3 clinical trial, CMC activities including manufacturing validation, and non-clinical studies. In addition to the base, the proposed contract also includes multiple contract options that may be activated by bilateral modification to this contract that will support completing the Phase 3 clinical trial, non-clinical studies, microbiology studies, a pediatric study, manufacturing development (CMC and reformulation), and regulatory (BLA submission and approval), quality assurance, management, and administrative activities. The R&D effort for exebacase will progress in specific stages that cover the base performance period and five option periods, which are discrete work segments. CLINs 0001 through 0005 are cost shared between the U.S. government (USG) and ContraFect and CLIN 0006 is to be fully funded by the USG.

The Contractor must achieve a defined end-product in each discrete work segment, as outlined in the Statement of Work (SOW) and Milestones in this contract, before the Government will consider exercising any of the follow-on options. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables specified under Section F of this contract. The GO/NO-GO Contract Milestones and Decision Gates will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option segment(s). The base and option period segments under Contract Line Item (CLIN) 0001, CLIN 0002, CLIN 0003, CLIN 0004, CLIN 0005 and CLIN 0006 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, shall only be used for the scope of work covered in each discrete work segment (i.e., the base period work segment and each option work segment). The periods of performance listed under each of the CLINs under Article B.2 and Article B.3 below are estimated time periods. Those individual time periods may be extended to complete the tasks required under each work segment. It is possible that more than one option period (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently.

B.2 BASE PERIOD

1. The total estimated Government cost of the base period of this Contract is $9,767,226.

2. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR52.215-2 (Jun 2020), Audit and Records – Negotiation and incorporated by reference into the contract in SECTION I.

3. The amount currently obligated will cover base performance of the contract through February 14, 2022. The period of performance may be adjusted with mutual agreement.

CLIN	Est. Period of Performance	Supplies/Services	BARDA Share	ContraFect Share	Total (BARDA share plus ContraFect share)
0001	15 March 2021 through 14 February 2022	Conduct a Phase 3 clinical trial, supportive manufacturing, futility analysis (60%) will be conducted and reviewed by the DSMB	$ 9,767,226	$ 31,056,909	$ 40,824,135

B.3. OPTION PERIODS

B.3.1 COST REIMBURSMENT OPTIONS

a. The contract includes optional, cost reimbursement CLINs 0002, 0003, 0004, 0005 and 0006. The Government may exercise Option Periods in accordance with FAR 52.217-9 Option to Extend the Term of the Contract (March 2000), as set forth in Section I of the contract.

b. Unless the government exercises its option pursuant to the option clause contained in ARTICLE I.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTONS C and F, for the price set forth in ARTICLE B.2 of the contract.

c. The Government may modify the contract unilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with FAR 52.217-9.

d. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The tentative time frame for period of performance and estimated cost of the contract will be increased as set forth below:

CLIN	Estimated Period of Performance	Supplies/Services	Government Share	ContraFect Share	Total Estimated Cost
0002	[***]	[***]	[***]	[***]	[***]
0003	[***]	[***]	[***]	[***]	[***]
0004	[***]	[***]	[***]	[***]	[***]
0005	[***]	[***]	[***]	[***]	[***]
0006	[***]	[***]	[***]	[***]	[***]
	TOTAL (CLIN 0001-0006)		**$86,807,228**	**$84,098,157**	**$170,905,385**

B.4 ESTIMATED COST - COST SHARING

This is a cost-sharing contract. The total estimated cost sharing for performing the work in the Base (CLIN 0001) and in optional CLINs (CLIN 0002-0006) is established in the above schedule, B.3.1. For further provisions regarding the specific cost-sharing arrangement, see the ADVANCE UNDERSTANDINGS Article in SECTION B.6(i) of the Contract.

B.5. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer or set forth in the Statement of Work, the cost of the following items or activities shall be unallowable as direct costs:

1) Acquisition, by purchase or lease, of any interest in real property;

2) Special rearrangement or alteration of facilities;

3) Accountable Government Property (see the HHS Contracting Guide for Control for Government Property incorporated by Section G.9. of this contract);

Note: this includes the lease or purchase of any item of general purpose office furniture or office equipment regardless of dollar value.

4) Purchase or lease of scientific instruments or equipment over $10,000 except for instruments and equipment specifically included in the Statement of Work;

5) Travel to attend general scientific meetings/conferences;

6) Printing Costs (as defined in the Government Printing and Binding Regulations);

7) Overtime (premium) compensation

8) Entering into certain types of subcontracting arrangements (See Section B.5(c) for specific obligations). Note that most consulting agreements require CO's written consent.

9) Foreign Travel (see Subparagraph b.3);

10) Light Refreshment and Meal Expenditures—Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least [***] in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

b. Travel Costs

1) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract will be solely the responsibility of the Contractor.

B.6. ADVANCE UNDERSTANDINGS

a. **Technical Visits**

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may, at the Government's sole cost and risk, conduct a technical visit of Contractor's or Subcontractor's facility. Technical visits under this Section shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the allowable cost requirements in FAR Subpart 31.2. The Government's representative(s) shall conduct their visits during normal business hours, of the production areas being utilized in performance on the Contract. The Government acknowledges that if the Government's representative obtains access to information that constitutes the trade secrets, confidential commercial or financial information of Contractor or Subcontractor they shall not publish, divulge, disclose, or make known in any information coming to them in the course of employment or official duties. The Government's representative shall not copy, record or remove Contractor's or Subcontractor's trade secret, confidential commercial or financial information, or limited rights data without the express written authority of Contractor or Subcontractor.

Technical Visits shall not occur more than twice per twelve (12) month period and shall be limited to not more than three (3) individuals representing the Government, whose visits shall not exceed three (3) business days per visit. These limitations may only be exceeded with the mutual written consent of the Parties.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

b. **Security**

No security plan is required at this point for this effort. It is anticipated that a security waiver will be approved.

c. **Subcontracts**

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that is funded by the USG and is not a subcontract already in effect at time of contract award that:

- Is of the cost-reimbursement, time and materials or labor-hour type; or
- Is of the fixed price type and exceeds $250,000.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section.

The following subcontracts, which Contractor has entered into, are already in effect at time of contract award and will not be funded by USG:

1. [***]

The following subcontracts, which Contractor has entered into, are already in effect at time of contract award, and may be funded by USG under this contract, thereby requiring Contracting Officer's Authorization (COA) for any subcontract amendment or new statement of work:

[***]

d. **Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract.

e. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration (FDA), BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial information or Contractor's limited rights data outside of the United States Government. It also does not authorize the Government to provide or communicate deliverables or data to the FDA. All proprietary and confidential marking of deliverables shared with USG entities shall be maintained and not obscured or excerpted from documents. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General and FAR 52.227-14, Rights in Data — Alt. II regarding the government's rights and obligations with respect to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

Limited Rights Data is defined as data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government.

This notice shall be marked on any reproduction of these data, in whole or in part.

f. **Approval of Human and Animal Protocols**

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval prior to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than ten (10) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

The protocol for the Phase 3 Study No.CF-301-105 (Study) that the government will partially fund under CLIN 1 of this Contract: 1) has been approved or will be approved by cognizant Institutional Review Boards; 2) has been reviewed and commented on by the FDA and such comments addressed by Contractor (see documents evaluated by BARDA during negotiations); and 3) as of the effective date of this Contract, patient enrollment for the Study is underway. ContraFect shall provide to BARDA the final Phase 3 study protocol, however the approval/authorization requirements of this advanced understanding, Article F.2., Deliverables, and Article H.1.2, Clinical Terms, below shall not apply to this Study.

g. **Rights in Data**

The contract will incorporate the FAR Clause 52.227-14, Rights in Data—General and FAR Clause 52.227-14, Rights in Data – Alt. II. The Contractor is advised to review the Government's rights and obligations with respect to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

h. **Cost Sharing**

1. This is a cost-sharing contract. Monies shall be provided for the total cost of performance from BARDA and ContraFect Corp.

2. BARDA shall provide monies in an amount not to exceed $9,767,226 for the base period. The Contractor's share of the BASE period is estimated at $31,056,909.

3. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.

4. Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program). The Contractor shall report the organization's share of the costs expended by category, on the Financial Report of Individual Project/Contract as referenced in the CONTRACT FINANCIAL REPORT Article in SECTION G of this contract.

5. Contractor's entitlement to reimbursement for the Government's share under this Contract is not contingent upon Contractor's cost share equaling any specific ratio or percentage of total estimated costs.

6. "Flow down" requirements of FAR and other clauses set forth in the Contract shall not apply topre-existing subcontracts and subcontracts funded by Contractor's share.

7. The consent to subcontract requirements of this Contract shall not apply to any subcontracts that will be funded by Contractor's share. The cost principles set forth in FAR 31.2 and the provisions of HHSAR 352.231-70 Salary rate limitation (December 2015) do not apply to costs funded by Contractor's cost share.

8. Inventions made with Contractor funds hereunder shall not be considered "Subject Inventions" under FAR 52.227-1, Patent Rights-Ownership by the Contractor.

9. The Government shall have the opportunity to observe audits, site visits or inspections with the Contractor.

i. **Invoice Submission during end of Fiscal Year**

The government will not accept invoices for processing from Sep 6th through Oct 5th because of end of year fiscal requirements. Any invoices received from September 6th through October 5th will be canceled and returned to the Contractor for resubmission beginning on October 6th.

k. **Contractor Consent to Go/No-Go Decision**

This is a cost-sharing contract. The Government's discretion to exercise options for periods beyond the base period may only be exercised if Contractor and Government agree that the Milestones of the current base or option period(s) have been accomplished. Following Contractor's notification to the COR that all Milestones of the current base or option period(s) have been achieved, the Government may, at its sole discretion, exercise its right to award the next option period.

l. Disclaimer of Implied Licenses

Except as expressly provided in this Contract or another agreement to which the government is a party, no right or license is granted to the government hereunder by implication, estoppel, or otherwise to any intellectual property owned or controlled by the Contractor, its subcontractors, or its licensors.

m. Recognition of Contractor Control Over Development Program

As the drug sponsor, Contractor shall have sole discretion over the development of exebecase and regarding how to respond to Government's comments concerning deliverables hereunder. The Government shall not require Contractor to change a submission to FDA or other submission that may impact the development of exebecase. An FDA-specified deadline and/or IND reporting timelines will override any BARDA review, comment, approval, response, availability, etc. if waiting for such action by Contractor would result in the deadline being missed.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work attached to this contract as Attachment 1 (Section J-List of Attachments).

C.2. REPORTING REQUIREMENTS

Refer to Section F.2 for specific instructions regarding Reporting Requirements.

C.3. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contract Officer, the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise mutually agreed upon by the Government and the Contractor or determined by the Contracting Officer. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded in eRoom by the Contractor within [***] after the conference call is held.

C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may include face-to-face meetings with BARDA in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and Government personnel as required by the COR in order to facilitate review of contract activities.

a. Kickoff Meeting

The Contractor and Government shall conduct a kickoff meeting within [***] after contract award to review HHS procedures, processes and expectations. Contractor shall provide an itinerary/agenda no later than [***] before the meeting. Minutes from the kickoff meeting must be provided within [***] of the event.

b. Quarterly and Ad-Hoc Meetings

At the discretion of the CO or COR, not more than four times annually, unless mutually agreed upon by the parties, the Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may be conducted via teleconferences or face-to-face meetings in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the other provisions of this Contract, the Contractor must provide data, reports, and presentations to and Government personnel and BARDA support service contractors subject to confidentiality agreements compliant with the terms of this Contract, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least [***] in advance of face-to-face meeting.

Contractor shall provide a meeting summary to the BARDA COR no later than [***] after the meeting.

c. Face-to-Face Project Review Meetings

Not more frequently and semi-annually, unless mutually agreed upon by the parties, the Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC, or alternatively upon agreement of the parties a virtual or remote meeting due to public health reasons. The Contractor will be responsible for updating the BARDA program on technical progress under the Statement of Work. Presentation must be delivered [***] prior to the scheduled meeting.

C.5 RISK MANAGEMENT

The Contractor shall establish and maintain an active, enterprise-wide risk management system as well as a specific risk management plan that includes the SOPs governing risk management, a description of the risk management activities required to oversee the project across its range of scope, and the processes for reviewing completed risk mitigations. The Contractor shall complete risk management documentation for the program as applicable, such as:

1. Preliminary hazard analyses as necessary for each product component
2. Design, user, and process FMEA plans
3. Risk control plans to verify the proposed mitigations

C.6 REGULATORY ACTIVITIES

The Contractor shall provide the COR the opportunity to review and comment upon any draft documents, including draft pre-submission packages, and meeting requests, to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with [***] for review and comments. An acceptable version shall be provided to the COR prior to FDA submission.

The Contractor shall provide the COR initial draft minutes and final draft minutes of any—meeting with the FDA and other regulatory agencies.

The Contractor shall communicate the dates and times of any meeting with the FDA and other regulatory agencies to the COR and ensure participation for appropriate COR and BARDA SME staff to attend the meetings.

The Contractor shall forward Standard Operating Procedures (SOPs) upon request from Contracting Officer's Representative /Contracting Officer.

The Contractor shall work to support BARDA in development of FDA submissions and meeting for seeking aPre-Emergency Use Authorization if deemed necessary by BARDA. The support may require the Contractor to develop unique deliverables other than the ones related to the SOW for submission to the FDA by BARDA.

The Contractor shall support FDA audits. Within [***] of receipt of a report from the FDA of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

C.7 QUALITY

The Contractor shall establish and maintain a Quality Management System with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor shall establish routine internal reviews, documentation, and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor shall contract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D – PACKAGING, MARKING, AND SHIPPING

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

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. On request, the CO will make the full text available. Also, the full text of a clause may be accessed electronically at: https://www.acquisition.gov/FAR (for the FAR) and HHSAR clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

FAR Clause	Title and Date
FAR 52.246-3,	Inspection of Supplies – Cost-Reimbursement (May 2001)
FAR 52.246-5,	Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-9,	Inspection of Research and Development (Short Form) (April 1984)
FAR 52.246-16,	Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will take place at a location designated by the Contracting Officer or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
O'Neill House Office Building
Washington, DC 20515

a. **Site Visits and Inspections**

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract. The Government acknowledges that the Government's representative may thereby obtain access to information that constitutes the trade secrets or confidential commercial and financial information of Contractor or Subcontractor. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner outside the Government, or to any extent not authorized by law, any information coming to them in the course of employment or official duties, while conducting such inspection. The Government's representative shall not copy, record or remove Contractor's or Subcontractor's trade secret, confidential commercial or financial information, or limited rights data from such site without the express written authority of Contractor or Subcontractor.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance:

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within [***] detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within [***].
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the Government exercises the Options Period(s) pursuant to the Option Clause in Section I.3 of the contract, the period of performance shall be increased as shown in the table in Section B.3.

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in the Statement of Work, Attachment 1, set forth in Section J—List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the COR, of each of the deliverables described in Section F and Section J.

All deliverables and reporting documents listed within this Section shall be delivered electronically (as defined in Section F.3 Electronic Submission) to the CO, CS, and the COR unless otherwise specified by the CO.

Unless otherwise specified by the CO, the deliverables identified in this Section F shall also be delivered electronically to the designated eRoom along with a concurrent email notification sent to the CO, CS, COR, and Alternate COR stating delivery has been made.

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). Hard copies of deliverables and reports furnished to the Government under the resultant Contract (including invoices) shall be addressed as follows:

HHS/ASPR/BARDA/CMA:

ATTN: James Bowers (Contracting Officer)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Research and Development Authority (BARDA)
Contract Management and Acquisition (CMA)
O'Neill House Office Building
Washington, DC 20515
Email: [***]

HHS/ASPR/BARDA:

ATTN: Kensey Amaya, Ph.D. (COR)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research & Development Authority (BARDA)
O'Neill House Office Building
Washington, DC 20515
Email: [***]

Contract Data Requirements List (CDRLs)

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	• Within [***] after contract award. • Contractor shall provide itinerary, slides, and agenda to CO and COR at least [***] in advance of meeting. COR approves distributes itinerary and agenda within [***]. • Contractor provides meeting minutes to CO and COR within [***] after the meeting. The CO and COR reviews, comments, and the COR approves minutes within [***] of the event.
02	Integrated Master Schedule (IMS)-Gantt	The Contractor shall provide an IMS including WBS, critical path, and milestones.	• Contractor shall provide the draft IMS-Gantt within [***] of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report. • Contractor must address, in writing, all concerns raised by the COR in writing and provide response to the CO and COR.
03	Risk Management Plan	The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance. See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• Due within [***] of contract award. • Contractor provides updated Risk Management Plan in Monthly Progress Report. The COR shall provide Contractor with written comments in response to the submitted plan. Contractor must address in writing, all reasonable concerns raised by the COR within [***] of Contractor's receipt of COR's concerns to receive CO approval.
04	Biweekly Teleconference Meetings	The Contractor shall participate in teleconferences every two weeks with the CO and the COR to discuss the performance of the contract.	• Contractor provides agenda and slides to the CO and COR no later than [***] in advance of meeting. The COR approves and distributes agenda to USG subject matter experts prior to meeting.

			• Contractor provides meeting minutes to the CO and COR within [***] following the meeting. The CO and COR reviews, comments, and the COR approves minutes within [***] following the meeting.
05 (monthly) 06 (annual)	Monthly & Annual Progress Reports	Monthly and Annual Progress report shall address the progress occurring over the corresponding period of time. See below, ARTICLE F.2(2) "Detailed Description of Select Contract Deliverables," for detailed instructions.	• Monthly Reports shall be submitted on the [***] with an Annual Report submitted on [***]. • When the [***] or [***] falls on a weekend or a US Holiday, the reports will be due the next business day. • Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due. • The CO and the COR will review the monthly reports and provide feedback within [***] of receiving the report. The COR approves acceptance of monthly and annual reports. • The CO and the COR will review the annual reports and provide feedback within [***] of receiving the report. The COR approves acceptance of monthly and annual reports.
07	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or subcontractors. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	• Contractor shall provide itinerary, slides, and agenda to CO and COR at [***] in advance of site visit. The COR approves and distributes itinerary and agenda within [***]. • Contractor provides meeting minutes to the CO and the COR within [***] after the meeting. The CO and COR reviews, comments, and the COR approves minutes within [***].

08	Final Report	A draft Final Report containing a summation of the work performed and the results obtained for the entire contract Period of Performance (PoP). The draft report shall be duly marked as 'Draft'. The Final Report incorporating BARDA feedback on the draft Final Report and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'. See below, ARTICLE F.2(2) "Detailed Description of Select Contract Deliverables," for detailed instructions..	• Contractor shall provide a draft Final Report [***] before the end of the PoP and the Final Report on or before the completion date of the PoP. • Subcontractor prepared reports shall be submitted to the COR and CO for review and comment no later than [***] days after receipt by the prime contractor • COR shall provide feedback on draft report within [***] of receipt, which the Contractor shall consider incorporating into the Final Report • Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.
09	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study Protocols to the COR for evaluation. (The CO and COR reserves the right to request within the period of performance a non-proprietary Study Protocol for distribution within the US Government.	• The Contractor will submit all proposed protocols to the CO and COR at least [***] prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the CO and COR to the satisfaction of the COR before study execution and provide the CO and COR a revised draft protocol that addresses the CO's comments and requested changes.

			• After receiving the revised Study Protocol that satisfies the COR, the CO will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. • Contractor shall not proceed with any study protocol until the COR gives its approval and the Contractor has provided the CO and COR with a final and approved Study Protocol.
10	Clinical Study Status Update	Contractor shall provide COR with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Contractor will provide proposed format for the COR's review and approval. See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• Update will be submitted by e-mail or other electronic format to be provided by the COR by the end of [***]. • When the [***] falls on a weekend or US Holiday, the update will be due the next business day. • Updates, to the extent they are available, will be presented during [***] teleconferences. • If no changes have occurred since the prior update only a simple statement that there is no new data is required.
11	Draft and Final Reports for Clinical and Non-Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the CO and COR for review and comment. See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• Within [***] after completion of analysis and at least [***] prior to submission to FDA. Subcontractor prepared Draft Final reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than [***] after receipt by Contractor.

			• The CO or COR shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within [***] after the submission to BARDA. Contractor shall consider revising Draft reports to address CO's recommendations. If corrective action is recommended, Contractor must address, in writing, all reasonable concerns raised by the CO in writing within [***]. • Final FDA submissions shall be provided to the CO and COR concurrently or no later than [***] after submission to the FDA.
12	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule. Contractor shall notify BARDA of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high-level management strategy for risk mitigation.	• As needed and communicated by the COR/CO.
13	Incident Report	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the CO and COR.	• Within [***] of activity or incident or within [***] for a security activity or incident via email or telephone, with written follow-up to the CO and COR. Additional updates due within [***] of additional developments. • Contractor shall submit, within [***], a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO, within [***] of receiving such concerns in writing.

14	Standard Operating Procedures	The Contractor shall make internal and, to the extent possible, subcontractor Standard Operating Procedures (SOPs) available for review electronically.	• Upon request from the CO.
15	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to the CO and COR. All documents shall be duly marked as either “Draft” or “Final”.	• Contractor shall provide written summary of any FDA correspondence within [***] of correspondence.
16	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate government staff to observe the FDA meetings. Government staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts). See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements. FDA deadlines and timelines will govern and Contractor may proceed with any meeting if Government staff is unavailable.	• Contractor shall schedule upcoming FDA meetings, so at a minimum the CO, COR, and RQA persons from BARDA can attend. Additionally, a pre-meeting needs to be held with BARDA to review slides and discuss meeting strategies. • Contractor shall notify the CO and COR of upcoming FDA meeting within [***] of scheduling. • Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within [***] of receipt. All documents shall be duly marked as either “Draft” or “Final”.

17	FDA submissions	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final". See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• The timeline for BARDA review of Contractor FDA documents will be discussed and confirmed by both parties at time of submission to BARDA. • The Contractor shall consider revising their documents to address BARDA's concerns and/or recommendations prior to FDA submission. If Contractor does not address CO/BARDA recommendations, then the Contractor shall provide a justification / explanation why BARDA recommendation is rejected. • Final FDA submissions shall be submitted to the CO and COR concurrently or no later than [***] from its submission to FDA.
18	FDA Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector. See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• Contractor shall notify the CO and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit/audit if the FDA does not provide advanced notice. • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within fi[***] of receiving correspondence from the FDA or third party. • Within [***] of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

19	Manufacturing Campaign Reports	Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA. The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG	• Contractor will submit to BARDA Manufacturing Campaign Reports at least [***] prior to FDA submission. • If corrective action is recommended, Contractor must address, in writing, all concerns raised by BARDA within [***]. • Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission. • Final FDA submission shall be submitted to BARDA concurrently or no later than [***] after submission to the FDA.
20	QA Audit Reports	BARDA Quality group and /or their qualified representatives reserves the right to observe in QA audits conducted by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	• Contractor shall notify the CO and COR [***] in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. • Contractor shall notify the CO and COR within [***] of report completion.

21	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the CO and COR. Contractor shall also accommodate any 'for cause' audit if and when there are potential issues identified in the program during the period of performance. Such issues include but are not limited to stability failures, GLP issues etc. If the CO, COR, Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the CO and COR.	• If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within [***] of the audit. • The CO and COR will review the report and provide a response to the Contractor with [***]. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.
22	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government. See below, ARTICLE F.2. (2) Detailed Description of Select Contract Deliverables, for specific requirements.	• Contractor shall provide technical document within [***] of COR's request. Contractor can request additional time on an as needed basis. • If corrective action is recommended by the COR, the Contractor must address, in writing, concerns raised by the COR to the COR and CO in writing within [***].

23	Raw Data or Data Analysis	Contractor shall provide raw data and/or data analysis from completed studies to the CO and COR upon request. Contractor shall address and adjudicate all concerns from BARDA review of the data/analysis and amend the reports as required.	• Contractor shall provide data or data analysis to the CO and COR within [***] of request. Contractor shall amend the reports if required and adjudicate all comments.
24	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the CO and COR for review prior to submission.	• Contractor must submit all manuscript or scientific meeting abstract to the CO and COR within [***] for manuscripts and [***] for abstracts. • Contractor must address in writing all concerns raised by the CO and COR in writing. • Final submissions shall be submitted to the CO and COR concurrently or no later than [***] after its submission.
25	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.	• With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO and COR has received and approved an advanced copy of any draft press release to this contract not less than [***] prior to the issuance of the press release. The CO shall reply with comments within [***] of receipt of the draft press release. Should no comments be forthcoming from the CO by end of the [***], Contractor will be permitted to issue the press release

- If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.
- Any final press releases shall be submitted to the CO and COR no later than [***] prior to its release.

NOTE: Pursuant to federal law, no Government personnel shall publish, divulge, disclose, or otherwise make known to anynon-Government entity any Contractor data marked according to FAR 52.227-14, and/or FAR 52.227-14, Alt II unless permitted to do so by law or regulation.

Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Section F of this contract, and in the Statement of Work, attached to this contract (see Section J-List of Attachments).

i. **Monthly Progress Report**

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this Section. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).

- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.

  a. This Section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.

  b. This Section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

  A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due. The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under Section F.2. of this contract. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE -

- A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance
- audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

2. A summary of any Subject Inventions per the requirements under FAR Clause52.227-11.

iii. **Draft Final Report and Final Report**

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the Deliverables Chart in Section F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under SECTION F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in Section F.2. of the contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary of salient results achieved during the performance of the contract.

v. **Audit Reports**

Within [***] of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report and as related to activities funded under this contract.

vi. **Periodic Document Review**

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within [***] of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

vii. **Risk Management Plan**

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within [***] of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The COR shall provide Contractor with a written list of concerns in response plan submitted

Contractor must address, in writing, all concerns raised by COR within [***] of Contractor's receipt of COR's concerns.

B. Deliverables Arising from FDA Correspondence

i. **FDA Meetings**

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to observe the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify BARDA of upcoming FDA meeting within [***] of scheduling.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within [***] of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. **FDA Submissions**

The Contractor shall provide the COR all documents submitted to the FDA.

Contractor shall provide the COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor.
- If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to the CO and COR concurrently or no later than [***] of their submission to FDA.

iii. **FDA Audits**

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within [***] after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within ten (10) business days of a scheduled FDA audit or within [***] of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA, Subcontractor, or third party.
- Within [***] of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. **Other FDA Correspondence**

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within [***] of correspondence.

F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents to the appropriate folder onhttps://eroom.bardatools.hhs.gov/eRoom ("eRoom") which is the designated Government file sharing system. The Government shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b) (2) (ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in Section G – Contract Administration Data.

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

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (Aug 1989)

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

James Bowers (Contracting Officer)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Biomedical Advanced Research and Development Authority (BARDA)
Contract Management and Acquisition (CMA)
O'Neill House Office Building
Washington, DC 20515
301-956-6588
Email: [***]

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

ATTN: Kensey Amaya, Ph.D. (COR)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research & Development Authority (BARDA)
O'Neill House Office Building
Washington, DC 20515
Email: [***]

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

3) Performing technical evaluation as required;

4) Performing technical inspections and acceptances required by this contract; and

5) Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The key personnel specified in this contract are considered to be essential to work performance. At least [***] prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. Key personnel are not required to devote their full time to performance of the Contract. The parties may agree to modify the contract to add or delete key personnel.

G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the [***] after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under Section J entitled, “Financial Report of Individual Project/Contract,”.

f. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact:

CO	COR	PSC
James Bowers (Contracting Officer) HHS/ASPR/BARDA/CMA O’Neill House Office Bldg Washington, DC 20515 Email: [***]	Kensey Amaya, PhD COR HHS/ASPR/BARDA O’Neill House Office Bldg Washington, DC 20515 202-690-5746 Email: [***]	[***] & “e-Room”

The Contractor agrees to immediately notify the CO and COR in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

- The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.
- The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that:
- The costs the Contractor expects to incur under this contract in the next [***], when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or
- The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.
- As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.
- Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—
- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.
- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.
- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.
- The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
- An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.
- All invoice submissions shall be in accordance with FAR Clause52.232-25, Prompt Payment (Jan 2017).

h. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $10,000.
5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $10,000.
10. G&A - Cite rate and amount.
11. Total Cost (and applicable cost-shared ratio)
12. Fixed Fee (if applicable)
13. Total Cost Plus Fixed Fee

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs (e.g., transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract will be solely the responsibility of the Contractor

G.6. INDIRECT COST RATES

a) The following provisional rates are established and incorporated into the contract for the Government's reimbursement of indirect costs (include specific CLINS or Base period if needed) pending the establishment of final indirect cost rates in accordance with FAR 52.216-7. The provisional rates may be revised retroactively or prospectively during contract performance by mutual agreement of the contracting officer, or cognizant auditor and the contractor at either party's request, to prevent substantial overpayment or underpayment.

Rate Type	Provisional Rate	Ceiling	Allocation Base
Fringe Benefits	[***]	[***]	Total Salaries and Wages
G&A	[***]	[***]	Total Direct Costs

b) Notwithstanding the provisions of FAR 42.704, ceilings are hereby established on indirect costs reimbursable under this contract. Therefore, the Government will not be obligated to pay any additional amounts if the final indirect cost rates developed by the cognizant audit activity based on actual allowable costs exceed the ceiling rates set forth above. In the event the final indirect cost rates are less than the above-established ceiling rates, the negotiated final rates shall be reduced to conform to the lower rates.

c) In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rate proposal to the contracting officer and the cognizant auditor within the six-month period following the end of each of its fiscal years during the period of contract performance. The contracting officer may grant, in writing, reasonable extensions, for exceptional circumstances only, when requested in writing by the contractor.

G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

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

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

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

https://www.cpars.gov/

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required [***] time frame.

G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, the Contractor shall comply with the provisions of HHS Publication, “HHS Contracting Guide for Control of Government Property,” which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

Among other issues, this publication provides a summary of the Contractor’s responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, “HHS Contracting Guide for Control of Government Property,” which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, “Report of Government Owned, Contractor Held Property” for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is attached to this contract (see Section J- List of Attachments). Title will vest in the Government for equipment purchased as a direct cost.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed-down as applicable to subcontracts funded by the Government and agreements entered into after contract award.

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial*and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Section F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Section F.2 of this contract.

Execution of clinical and non-clinical studies occurring after contract award and funded by the Government requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have rights to all protocols developed with USG funding under the contract, data resulting from execution of these protocols, and final reports funded by BARDA under this contract as set forth in FAR clauses 52.227-14 and 52.227-14 Alt. II of this contract. The Government reserves the right, subject to the provisions of FAR 52.227-14, FAR 52.227-14 Alt II and HHSAR 352.224-71, to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary except that the Government will not release or otherwise publicly disclose any protocol, data resulting from execution of these protocols or final reports prior to its initial release and public disclosure by Contractor, and all proprietary and confidential marking of shared deliverables shall be maintained and not obscured or excerpted. Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical-research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

a. These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non-clinical research (and Safety and Monitoring Issues) solely or partially funded by BARDA

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol.

They must also provide BARDA initial and annual documentation of continuing review and approval and federal wide assurance number.

The Contractor must ensure that the application, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
- All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).
- Termination or temporary suspension of the study(ies) for regulatory issues.
- Termination or temporary suspension of the protocol.
- Any change that is made in the specific IACUC approval for the indicated study(ies).
- Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify BARDA of any of the above changes within five (5) working days from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Non-Clinical Data and Safety Monitoring Requirements.

BARDA strongly recommends continued safety monitoring for all non-clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. Awardee should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA-sponsored studies of any type measure the risk and safety parameters that are elicited and provide a safety profile from the studies for future human risk assessment.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CRO's as BARDA deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by BARDA:

- IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
- For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
- Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
- Contractor should reduce the number of animals required for a study using power of statistics.

- Plans for the management of side effects, rules for interventions and euthanasia criteria.
- Procedures for assessing and collecting safety data were appropriate.
- If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure an integrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).
- Documentation that the Contractor and all required staff responsible for the conduct of the research have received training in the protection and handling of animals, or that the CRO has the required documentation.
- Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract.
- Provide justification for whether studies require good laboratory practice (GLP) conditions.
- Provide justification for whether studies will be classified asnon-pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to BARDA for evaluation and comment in conjunction with the protocol. Execution of non-clinical studies requires written authorization from BARDA in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals: http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf

USDA Animal Welfare Act:
https://www.aphis.usda.gov/animal_welfare/downloads/bluebook-ac-awa.pdf

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Government and the Contractor and apply to all grants and contracts which involve clinical research funded by the Government under this Agreement.

BARDA shall have rights to all protocols, data generated from the execution of protocols, and creation of final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary except that BARDA will not release or otherwise publicly disclose any protocol, data resulting from execution of these protocols or final reports prior to its initial release and public disclosure by Contractor and all proprietary and confidential marking of shared deliverables shall be maintained and not obscured or excerpted.

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Within 30 days of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol or have formally accepted the review of a central IRB/IEC. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document or federal wide assurance number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC or a formally recognized central IRB/IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the COR copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify the COR and CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is considered minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following.

- **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
- **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to BARDA within thirty (30) days of reviews or meetings.

iii. **BARDA Protocol Review Process Before Patient Enrollment Begins.** The COR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC-approved informed consent document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this Section of this contract.

iv. **Investigational New drug or Investigational Device Exemption Requirements**

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's Representative (COR) as follows:

i. Expedited safety report of unexpected or life-threatening experience or death:

A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than [***] after the IND sponsor's receipt of the information, must be submitted to the COR within [***] of FDA notification.

ii. Expedited safety reports of serious and unexpected adverse experiences:

A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than [***] after the IND sponsor's receipt of the information, must be submitted to the COR within [***] of FDA notification. For medical devices, adverse events should be reported under the MedWatch (MDR) program with reporting timelines of 5 days for serious adverse events or 30 days for reportable events.

iii. IDE reports of unanticipated adverse device effect:

A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the COR within [***] of FDA notification.

iv. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

v. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually. In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) business days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

vi. Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the COR and the Contractor.

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current federal wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FW' via designation as agents of the institution or via individual investigator agreements (see OHRP website at: https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/guidanceonalternativetofwa.pdf).

d. If at any time during the performance of this contract, the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.3. HUMAN MATERIAL

The acquisition and supply of all human material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material. The Parties mutually understand and agree that the DLAs used by Contractor under this Agreement are not and shall not be considered human material and therefore shall not be subject to the Uniform Anatomical Gift Act, or any other regulations regarding the collection or use of human material.

The Contractor shall provide written documentation that all human material obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS
HOTLINE
P.O. Box 23489 Washington, D.C. 20026

H.5. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.6. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated with USG funding under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right, subject to the provisions of FAR 52.227-14, FAR 52.227-14 Alt II and HHSAR 352.224-71, to review any other data determined by DHHS to have been generated with USG funding. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.7. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, and that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.9. ACCESS TO DOCUMENTATION/DATA

Subject to the provisions of FAR 52.227-14 and 52.227-14 Alt. II, and HHSAR 352.224-71, the Government shall have physical and electronic access to all documentation and data first generated in the performance of this contract using Government funding, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

H.10. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.11. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this contract shall be released or publicized as a publication without providing BARDA with [***] advanced notice and an opportunity to review the proposed publication.

[***] Any publication containing data generated under this contract must be submitted for BARDA review no less than [***] for manuscripts and [***] for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

> "This project has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50121C00021."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than [***] prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No.75A501212C00021."

H.12. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

H.13. PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at: https://www.govinfo.gov/app/details/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b/context

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: https://www.govinfo.gov/content/pkg/FR-2002-09-26/pdf/02-23965.pdf

H.14. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services funded by the Government under this contract.

H.15. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded by the Government under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.16. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.17. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within [***] of activity or incident or within [***] for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within [***] of additional developments.
- Contractor shall submit within [***] a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within [***].

H.18. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP) (21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.19. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.20. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity except that Contractor shall not have to submit for review and comment any existing and/or approved protocol or informed consent documents.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.21. SHARING RESEARCH DATA

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

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

H.22. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

The Contractor shall not use any funds obligated under this contract for any abortion. The Contractor shall not use any funds obligated under this contract for the following:

The creation of a human embryo or embryos for research purposes; or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

The Contractor shall not use any Federal funds for the cloning of human beings.

H.23. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine’s (NLM) PubMed Central (PMC) an electronic version of the author’s final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author’s final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.24. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/cgi-bin/text-idx?SID=6615ebad97db608b6c5d09ab42646afc&mc=true&node=pt45.1.94&rgn=div5

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator’s reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.25 DISCLOSURE OF FINANCIAL PERFORMANCE AND TRANSFER OF TECHNOLOGY

This clause shall remain in effect during the term of the Contract.

a. Contractor Financial Performance

[***]

b. Post-award Transfer of Ownership of Technology

[***]

H.26. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.27. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73.

No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (https://www.ecfr.gov/cgi-bin/text-idx?SID=ac61478ec71499ea77bc55c4e698db07&mc=true&node=pt42.1.73&rgn=div5) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/regulations.html

H.28. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with [***] advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within [***] of the audit.
- COR and CO will review the report and provide a response to the Contractor with [***].
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

PART II SECTION I CONTRACT

CLAUSES

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

General Clauses for Cost-Reimbursement Research and Development Contract

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

FAR Clause	Date	Clause Title
52.202-1	Jun 2020	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
52.203-7	Jun 2020	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
52.203-13	Jun 2020	Contractor Code of Business Ethics and Conduct
52.203-14	Jun 2020	Display of Hotline Poster(s)
52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Oct 2018	System for Award Management Maintenance
52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
52.204-25	Aug 2020	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Service or Equipment
52.209-6	Jun 2020	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
52.210-1	Jun 2020	Market Research
52.211-5	Aug 2000	Material Requirements

52.215-2	Jun 2020	Audit and Records – Negotiation
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-11	Jun 2020	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
52.215-13	Jun 2020	Subcontractor Certified Cost or Pricing Data—Modifications
52.215-14	Jun 2020	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-16	June 2003	Facilities Capital Cost of Money
52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits(PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
52.215-23	Jun 2020	Limitations on Pass-Through Charges
52.216-7	Aug 2018	Allowable Cost and Payment Note: the cost principles set forth in FAR 31.2 do not apply to costs funded by Contractor’s cost share
52.216-8	Jun 2011	Fixed Fee
52.219-8	Oct 2018	Utilization of Small Business Concerns
52.219-9	Jun 2020	Small Business Subcontracting Plan
52.219-16	Jan 1999	Liquidated Damages – Subcontracting Plan
52.219-28	Nov 2020	Post-Award Small Business Program Representation
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
52.222-26	Sept 2016	Equal Opportunity
52.222-35	Jun 2020	Equal Opportunity for Veterans
52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
52.222-37	Jun 2020	Employment Reports on Veterans
52.222-38	Feb 2016	Compliance with Veterans’ Employment Reporting Requirements
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act

52.222-50	Oct 2020	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Jun 2020	Encouraging Contractor Policy to Ban Text Messaging While Driving
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
52.227-1	Jun 2020	Authorization and Consent, Alternate 1 (APR 1984)
52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights – Ownership by the Contractor
52.227-14 Alt. II	Dec 2007	Rights in Data – General – Limited Rights Notice
52.228-7	Mar 1996	Insurance – Liability to Third Persons
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment
52.232-33	Oct 2018	Payment by Electronic Funds Transfer–System for Award Management
52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes – Cost-Reimbursement Alternate V (Apr 1984)
52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Nov 2020	Subcontracts for Commercial Items
52.245-1	Jan 2017	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protégé Program
HHSAR	352.219-71	Jan 2010	Mentor-Protégé Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information § (c)(2)(i): none
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

The Government may extend the term of this contract by written notice to the Contractor within 30 days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

- If the Government exercises this option, the extended contract shall be considered to include this option clause.
- The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

FAR Clause 52.219-28, Post-Award Small Business Program Representation (Mar 2020)

a. *Definitions* As used in this clause—

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shallre-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of thisre-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

(1) The Contractor represents that it ☐ is, ☐ is not a small business concern under NAICS Code _____ assigned to contract number 75A50121C00021.

(2) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause*] The Contractor represents that it ☐ is, ☐ is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause*] The Contractor represents that it ☐ is, ☐ is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [*Complete only if the Contractor represented itself as a women-owned small business concern in paragraph (h)(3) of this clause.*] The Contractor represents that—

(i) It ☐ is, ☐ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (h)(4)(i) of this clause is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. *[The Contractor shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture:_____.]* Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern.[*Complete only if the Contractor represented itself as a women-owned small business concern eligible under the WOSB Program in (h)(4) of this clause.*] The Contractor represents that—

(i) It ☐ is, ☐ is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (h)(5)(i) of this clause is accurate for each EDWOSB concern participating in the joint venture. [The Contractor shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause.*] The Contractor represents that it ☐ is, ☐ is not a veteran-owned small business concern.

(7) [*Complete only if the Contractor represented itself as a veteran-owned small business concern in paragraph (h)(6) of this clause*] The Contractor represents that it ☐ is, ☐ is not a service-disabled veteran-owned small business concern.

(8) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause.*] The Contractor represents that —

(i) It ☐ is, ☐ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

(ii) It ☐ is, ☐ is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (h)(8)(i) of this clause is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [*The Contractor shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture:* _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

[*Contractor to sign and date and insert authorized signer's name and title.*]

(End of clause)

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause—

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

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

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

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

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

(b) Safeguarding requirements and procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. **Statement of Work**

   Statement of Work, dated February 11, 2021.

2. **Invoice/Financing Request Instructions for AMCG Cost-Reimbursement Type Contracts**

   Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Type Contracts, 2 pages.

3. **Financial Report of Individual Project/Contract, 1 page**

4. **Instructions for Completing Financial Report of Individual Project/Contract, 2 pages**

5. **Inclusion Enrollment Report**

   Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

6. **Research Patient Care Costs**

   Research Patient Care Costs, 1 page.

7. **Report of Government Owned, Contractor Held Property**

   Report of Government Owned, Contractor Held Property, 1 page. Located at: http://rcb.cancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf

ContraFect Announces BARDA Contract Award for Up to $86.8 Million and Provides Business Outlook

BARDA to provide funding for the ongoing Phase 3 DISRUPT study of exebacase for the treatment of patients with Staph aureus bloodstream infections

Results from the Phase 3 DISRUPT study interim futility analysis anticipated in H2 2021

Phase 3 DISRUPT study has the potential to serve as the basis for U.S. FDA product approval

Conference call to be held on March 12, 2021 at 8:30 a.m. ET

YONKERS, NY – March 11, 2021 — ContraFect Corporation (Nasdaq: CFRX), a clinical-stage biotechnology company focused on the discovery and development of direct lytic agents (DLAs) as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, today announced that it has been awarded a cost-share contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). Under the terms of the contract, the Company will receive $9.8 million in initial funding and up to an additional $77.0 million. The initial funding will be used to support ContraFect's ongoing pivotal Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) superiority study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis. Under the terms of the agreement, and if supported by Phase 3 DISRUPT study data, BARDA may provide the Company with additional funding upon achievement of key milestones to continue the advancement of exebacase through FDA product approval and completion of post-approval commitments.

"We are grateful for, and thrilled by, BARDA's support to fund the advancement of exebacase toward the completion of our ongoing Phase 3 study and a potential product approval. This award represents a critical milestone and a transformational infusion of funds for ContraFect. Exebacase, which received Breakthrough Therapy Designation last year from the FDA, is the first direct lytic agent in Phase 3 trials and the lead program of our DLA platform, representing a completely new medical modality to address life-threatening infectious diseases. We believe that this award, and the expected acceleration of Phase 3 study enrollment, provides ContraFect with strong momentum as we move toward the interim futility analysis, currently anticipated in the second half of 2021," said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect.

"Antibiotic-resistant infections are rising at an alarming rate, and developing effective medical countermeasures against these infections has become one of the most pressing health security challenges of this century," said BARDA Director Gary Disbrow, Ph.D. "ContraFect Corporation is the latest partner to work with BARDA on potential solutions to life-threatening infections and help save lives in future public health emergencies."

Overview of Programs and Anticipated Milestones

Exebacase: a first-in-class recombinantly-produced lysin with the potential to become a newstandard-of-care, compared to using antibiotics alone, for the treatment of *Staph aureus* bacteremia.

- In 2020, the Company began enrolling patients in the Phase 3 DISRUPT study and exebacase was granted Breakthrough Therapy designation by the FDA for the treatment of methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections, including right-sided endocarditis, when used in addition to standard-of-care anti-staphylococcal antibiotics in adult patients. The Phase 3 DISRUPT study is a randomized, double-blind, placebo-controlled clinical study conducted in the U.S. to assess the efficacy and safety of exebacase in approximately 350 patients with *Staph aureus* bacteremia, including right-sided endocarditis.
- Despite the onset of the COVID-19 pandemic shortly after the initiation of the DISRUPT study, the Company has continued to enroll patients and has expanded the number of clinical trial sites to over 40 sites across the United States. The pandemic has caused delays in patient enrollment, as hospitals have struggled to support intensive care units and the critical care of patients with severe COVID-19 infections. Assuming that the recent initiation of nationwide COVID-19 vaccinations expands to encompass a significant portion of the population, the Company believes the hospital burden will lighten during the first half of 2021 and expects an acceleration of DISRUPT study enrollment. ContraFect expects to conduct an interim futility analysis to assess the superiority of exebacase versus SOC alone, based on approximately 60% of the study population, in the second half of 2021. Topline data for the full study population are expected in 2022.

CF-370: a first-in-class, engineered lysin with the potential to become the first direct lytic agent in clinical development for the treatment of *Pseudomonas aeruginosa* infections.

- In 2020, the Company began IND-enabling activities to advance CF-370 towards clinical development and received a CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator) award for up to $18.9 million in non-dilutive capital to progress CF-370 through these activities.
- The Company continues to progress the IND-enabling studies of CF-370 towards completion and expects to initiate Phase 1 studies of CF-370 in the first half of 2022.

Amurin peptides: a new class of direct lytic agents with the potential to become an entirely new modality for broad-spectrum coverage of Gram-negative pathogens.

- Characterization of the Company's lead amurin peptides is ongoing and the Company expects to select an amurin peptide as its next IND candidate by the end of 2021.

Conference Call and Webcast Information

ContraFect will host a live conference call and webcast at 8:30 a.m. ET on March 12, 2021. To access the live conference call, please dial (866) 691-5817 and refer to conference ID 4278833. A webcast of the call will also be available under "Events" in the Investors & Media section of the ContraFect website at www.contrafect.com. The archived webcast will be available on the Company's website after the conference call.

About DISRUPT:

The Phase 3 DISRUPT study of exebacase is a randomized, double-blind, placebo-controlled clinical study conducted in the U.S. to assess the efficacy and safety of exebacase in approximately 350 patients with complicated *Staph aureus* bacteremia, including right-sided endocarditis. Patients enrolled in the Phase 3 study are randomized 2:1 to receive either exebacase or placebo, with all patients receiving SOC antibiotics. The primary efficacy endpoint of the study is clinical response at day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints include clinical response at day 14 in the All *Staph aureus* patients (MRSA and methicillin-sensitive *Staph aureus* (MSSA)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. An independent Data Safety Monitoring Board (DSMB) will conduct the interim futility analysis after 60% of the study population completes the Day 14 primary endpoint study visit.

About Exebacase (CF-301):

Exebacase is a recombinantly-produced lysin (cell wall hydrolase enzyme) with potent bactericidal activity against *Staph aureus*, a major cause of bloodstream infections (BSIs) also known as bacteremia. In the Company's Phase 2 study of exebacase, a pre-specified analysis of MRSA-infected patients showed that the clinical responder rate at day 14 in patients treated with exebacase was nearly 43-percentage points higher than in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOC antibiotics alone (p=0.010)). In addition to the higher rate of clinical response, MRSA-infected patients treated with exebacase showed a 21-percentage point reduction in 30-day all-cause mortality (p=0.056), a four-day lower mean length of hospital stay and meaningful reductions in hospital readmission rates. Exebacase is being studied in the Phase 3 DISRUPT superiority design study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis.

Exebacase has the potential to be a first-in-class treatment for *Staph aureus* bacteremia. Exebacase was licensed from The Rockefeller University and is being developed at ContraFect.

About CF-370:

CF-370 is an investigational first-in-class therapeutic candidate targeting *Pseudomonas aeruginosa (P. aeruginosa*), a Gram-negative pathogen. CF-370 has been engineered to bypass the outer membrane of the bacteria and to enable potent activity in human serum. The Company believes this is a significant milestone for direct lytic agents as native lysins are typically unable to penetrate the outer membrane of Gram-negative bacteria and consequently unable to work in vitro in human blood or in animal models. However, based on the proprietary methods the Company has identified and utilizes to engineer lysins, CF-370 has exhibited the hallmark in vitro features of the lysin class, including rapid and potent bactericidal activity, synergy with a broad range of standard of care agents and the eradication of biofilms in preclinical studies. The promising data from animal models support the potential therapeutic utility of CF-370 for the treatment of serious infections caused by *P. aeruginosa*, including hospital-acquired and ventilator-associated pneumonias and pulmonary exacerbations of cystic fibrosis.

About ContraFect:

ContraFect is a biotechnology company focused on the discovery and development of DLAs, including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. An estimated 700,000 deaths worldwide each year are attributed to antimicrobial-resistant infections. We intend to address life threatening infections using our therapeutic product candidates from our platform of DLAs, which include lysins and amurin peptides. Lysins are a new class of DLAs which are recombinantly produced antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics. Amurin peptides are a novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, including *P. aeruginosa*, *Acinetobacter baumannii*, and *Enterobacter* species. We believe that the properties of our lysins and amurin peptides will make them suitable for targeting antibiotic-resistant organisms, such as MRSA and *P. aeruginosa*, which can cause serious infections such as bacteremia, pneumonia and osteomyelitis. We have completed a Phase 2 clinical trial for the treatment of *Staph aureus* bacteremia, including endocarditis, with our lead lysin candidate, exebacase, which is the first lysin to enter clinical studies in the U.S. Exebacase, currently being studied in a pivotal Phase 3 clinical study, was granted Breakthrough Therapy designation by the FDA for the treatment of MRSA bloodstream infections, including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients.

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Activities related to exebacase during the period of performance under the contract will be funded in part with federal funds from HHS; ASPR; BARDA, under contract number 75A501212C00021.

Forward-Looking Statements

This press release contains, and our officers and representatives may make from time to time, “forward-looking statements” within the meaning of the U.S. federal securities laws. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. Examples of forward-looking statements in this release include, without limitation, statements regarding: ContraFect’s ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, expected receipt and use of funds from the BARDA contract, expected acceleration of Phase 3 study enrollment, timing of the interim futility analysis, whether DLAs are a new medical modality, potential for exebacase to become the new SOC used in addition to antibiotics, impacts from the COVID-19 pandemic on the DISRUPT study, timing of the CF-370 IND-enabling studies and the Phase 1 trial, expected timing of amurin candidate selection, whether exebacase has the potential to be a first-in-class treatment for exebacase, potential therapeutic utility of CF-370, whether ContraFect will address life-threatening infections using its DLA platform, whether lysins are a new class of DLAs which are recombinantly produced, antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics, whether amurins are a novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, and whether the properties of ContraFect’s lysins and amurins will make them suitable for targeting antibiotic-resistant organisms, such as MRSA and *P. aeruginosa.* Forward-looking statements are statements that are not historical facts, nor assurances of future performance. Instead, they are based on ContraFect’s current beliefs, expectations and assumptions regarding the future of its business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances that are difficult to predict and many of which are beyond ContraFect’s control, including

the occurrence of any adverse events related to the discovery, development and commercialization of ContraFect's product candidates such as unfavorable clinical trial results, insufficient supplies of drug products, the lack of regulatory approval, or the unsuccessful attainment or maintenance of patent protection and other important risks detailed under the caption "Risk Factors" in ContraFect's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Important factors that could cause actual results to differ include, among others, our ability to develop treatments for drug-resistant infectious diseases. Any forward-looking statement made by ContraFect in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, ContraFect expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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