DATE: August 30, 2019

TO: NCI Bid Board

FROM: Ronette Collins, Contract Specialist NCI/OA/SAB

RE: Bid Board Posting for a Requirement Titled: Characterize the function of rare PALB2 and BRCA2 variants identified in chordoma patients by generating knock-in mouse models using a CRISPR-based approach

The National Cancer Institute (NCI), Office of Acquisitions (OA), Integrative Tumor Epidemiology Branch (ITEB), Division of Cancer Epidemiology and Genetics (DCEG), Office of Acquisitions (OA) plans to procure services on a sole source basis in support of the NCI chordoma genetics study, characterize the function of PALB2 and BRCA2 variants identified in NCI chordoma studies from Rutgers Cancer Institute of New Jersey; 195 Little Albany Street; New Brunswick, NJ 08903.

Services will be procured on a sole-source basis under the authority of FAR 13.106-1 (b)(1).

Characterize the function of the rare PALB2 and BRCA2 variants identified in NCI chordoma studies by generating knock-in mouse models using a CRISPR-based approach. The result will greatly clarify whether the variants identified, as part of the government work, are related to the disease and therefore will determine whether this component of the current government work would have prevention of clinical significances.

If any interested party, especially a small business, believes they can meet the attached requirements, they may submit a proposal or quote. The response must be in writing and must contain information and material in sufficient detail to allow NCI to determine whether the party can fully meet this requirement. Offers must be submitted electronically (via email) to Contract Specialist, Ronette Collins, at ronette.collins@nih.gov in Microsoft Word or Adobe Portable Document Format (PDF), no later than 11:00 AM EST on Monday September 9, 2019. All responses must be received by the specified due date and time in order to be considered. OFFERORS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED. No collect calls will be accepted. Reference Solicitation # 75N91019Q00161 on all correspondence.

SOLE SOURCE:
Rutgers University reported the discovery of PALB2 as a major BRCA2 binding partner critical for its DNA repair and tumor suppression functions. Subsequently, the laboratory and others found a number of PALB2 mutations in familial breast cancer and Fanconi anemia (FA) patients, establishing PALB2 as a breast cancer tumor suppressor and a FA protein in its own right. Dr. Xia’s laboratory has been developing and conducting a number of experimental assays and models to discover the link(s) between the molecular actions of PALB2 in critical cellular processes and their abilities to suppress tumorigenesis, such as developing Palb2 and Brca1/2 conditional knockout and Palb2 knockin mouse models and conducting functional characterization of clinically relevant PALB2 mutations. These works are exactly in line with NCI/DCEG objective of characterizing the function of the germline PALB2 variants identified in the chordoma families and sporadic cases. He has access to laboratory and animal facilities that are critical for the completion of the proposed study. In addition, the laboratory has conducted several other functional assays in cell lines to measure the DNA damage and repair function of the PALB2 variants. Further, he has developed CRISPR mouse models to examine several PALB2...
variants for NCI/DCEG and the work is ongoing. The proposed work is a continuation of the ongoing functional work.

The proposed source (Rutgers Cancer Institute of New Jersey) is uniquely experience performing all of the technical requirements of the Statement of Work. The NCI/DCEG’s scientific investigation is ongoing, and the performance characteristics and quality of the needed services are required for maintaining the integrity of the stated investigation. A change would be disruptive to the ability to analyze NCI/DCEG’s cumulative results.

ATTACHED DOCUMENTS:

SF-18
Statement of Work

The following FAR Clauses/Provisions are incorporate as required by the John S. McCain National Defense Authorization Act (NDAA) for FY 2019, Public Law 115-232, Section 889(a)(1)(A).

The following FAR Clauses/Provisions are hereby added in full text.

FAR 52.204-24 - Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment

NOTE: Offerors are required to have an authorized individual self-certify and return attachment from FAR 52.204-24 along with the quote.

FAR 52.204-25 - Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

FAR 52.212-4 - Contract Terms and Conditions -- Commercial Items (October 2018)

FAR 52.212-5 - Contract Terms and Conditions Required to Implement Statutes or Executive Orders – Commercial.
REQUEST FOR QUOTATION

THIS IS NOT AN ORDER

1 REQUEST NO. 75N91019Q00161
2 DATE ISSUED 8/30/2019
3. REQUIREMENT/PURCHASE REQUEST NO. 
4. CERT. FOR NAT. DEF. SUPP. WITHDRAWN
5a. ISSUED BY NIH/NCI-OA 9609 Medical Center Drive, Room 1E132, Bethesda, MD 20892
5b. FOR INFORMATION CALL NO COLLECT CALLS
5c. NAME Ronette Collins, Contract Specialist
5d. TELEPHONE NUMBER 240-276-5745

6 DELIVER BY (Date) 6 months after award
7 FOR INFORMATION CALL OTHER (See Schedule)

8 a. NAME Ronette Collins
b. COMPANY NIH/NCI-OA 9609 Medical Center Drive Room 1E132 Bethesda MD 20892
9 a. DESTINATION Rockville MD 20850
8a. STRENGTH ADDRESS
b. STREET ADDRESS
8c. CITY Rockville
8d. STATE
8e. ZIP CODE 20850

10 PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a
ON OR BEFORE CLOSE OF BUSINESS (Date) IMPORTANT: This is a request for information, and quotations furnished are not offers. If you are unable to quote, please indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or services. Supplies are of domestic origin unless otherwise indicated by quote. Any representations and/or certifications attached to this Request for Quotations must be completed by the quoters.

09/09/2019 11:00 AM EST

11 SCHEDULE (Include applicable Federal, State and local taxes)

<table>
<thead>
<tr>
<th>ITEM NO.</th>
<th>SUPPLIES/SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>Procure services in support of the NCI chordoma genetics study, characterize the function of PALB2 and BRCA2 variants identified in NCI chordoma studies from Rutgers Cancer Institute of New Jersey; Please see attached Statement of Work (SOW). Period of performance shall be 12 months from the date of award.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Proposals must be submitted electronically (via email) to Contract Specialist, Ronette Collins, at ronette.collins@nih.gov in Microsoft Word or Adobe Portable Document Format (PDF), no later than 11:00 AM EST, on Monday September 9, 2019. Please reference 75N91019Q00124 on all correspondence.

This will be awarded as a Non-Severable Firm-Fixed Priced Purchase Order.

12 DISCOUNT FOR PROMPT PAYMENT

<table>
<thead>
<tr>
<th>a. 10 CALENDAR DAYS (%)</th>
<th>b. 20 CALENDAR DAYS (%)</th>
<th>c. 30 CALENDAR DAYS (%)</th>
<th>d. CALENDAR DAYS NUMBER</th>
<th>PERCENTAGE</th>
</tr>
</thead>
</table>

NOTE: Additional provisions and representations are not attached.

13 NAME AND ADDRESS OF QUOTER

a. NAME (Type or print) Ronette Collins
b. STREET ADDRESS NIH/NCI-OA 9609 Medical Center Drive Room 1E132 Bethesda MD 20892
c. COUNTY

d. CITY

e. STATE

14 SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION

15 DATE OF QUOTATION

16 SIGNER

a. NAME (Type or print)
b. TELEPHONE

c. AREA CODE

d. TITLE (Type or print)

18-121 STANDARD FORM 18 (REV. 6/95)

NSN 7540-01-152-9084

18-121

Previous edition not usable

Prescribed by GSA-FAR (46 CFR) 53.215-1(a)
STATEMENT OF WORK

1.0 TITLE

Characterize the function of rare PALB2 and BRCA2 variants identified in chordoma patients by generating knock-in mouse models using a CRISPR-based approach

2.0 BACKGROUND

General description: Chordoma is a rare bone tumor, with an age-adjusted incidence rate of less than 0.1 per 100,000 in the US. Chordoma is believed to originate from notochordal remnants and occurs almost exclusively in the axial skeleton where it is distributed nearly equally among cranial, vertebral and sacral sites. The tumor occurs more frequently in males than females (1.67:1) and in Caucasians than African-Americans (4:1) and is diagnosed at a median age of 58.5 years with a range from infancy to over 90. Little is known about either the molecular biology of chordoma or the etiologic factors that predispose to it. Chordoma is typically sporadic. However, several families with multiple relatives affected with chordoma have been described worldwide, suggesting hereditary factors may exist for this rare tumor. Since 1996, DCEG has taken the lead in genetic research of familial chordoma. DCEG has now recruited 10 chordoma families, which is the largest collection of chordoma families in the world, and are actively accruing new families worldwide. In addition, DCEG is also conducting a study to recruit sporadic chordoma cases from the United States and Canada. The goal of these studies is to identify chordoma susceptibility genes.

How the requirement evolved: DCEG previously identified germline T duplication as a major susceptibility mechanism in several chordoma families. However, genetic causes in the majority of sporadic cases and some chordoma families remain unknown. In an analysis to identify additional susceptibility genes in T duplication-negative families (five families with 19 cases) and sporadic cases (N=137) using whole-exome sequencing, DCEG identified a missense non-synonymous (NS) variant in PALB2 (c.1042C>A, p.Gln348Lys) that was present in two chordoma cases, one obligate gene carrier, and one case with juvenile pilocytic astrocytoma in one chordoma family. This variant was reported in 0.00023 and 0.00015 of individuals of European ancestry in ESP and The Exome Aggregation Consortium (ExAC), respectively. Five additional rare NS variants in PALB2 were identified, each in a single sporadic case. PALB2 is a binding partner of BRCA2 and functions as a tumor suppressor. One of the top biological processes involving BRCA2 is chordate embryonic development whose specific outcome is the progression of the embryo over time, from zygote formation through a stage including a notochord and neural tube until birth or egg hatching. DCEG has identified several rare NS variants in BRCA2 in a number of chordoma patients. Currently, DCEG is developing CRISPR mice models to examine whether these PALB2 variants identified in our patients have any functional relevance.

2.1 OBJECTIVE

Project Objectives: The overall goals of the chordoma studies are: 1) to identify additional major susceptibility genes for familial chordoma; and 2) to determine the prevalence of chordoma
susceptibility genes in sporadic chordoma. The specific aims for this procurement include: 1) maintaining \textit{PALB2} CRISPR mice until the number of mice in each genotype group is sufficient to allow us to compare phenotypes across different groups; 2) isolating RNA from \textit{PALB2} mice to investigate gene expression changes in \textit{PALB2} mutated mice; and 3) generating new knock-in mouse model to characterize the function of candidate \textit{BRCA2} variants identified in chordoma cases.

\section*{3.0. SCOPE}

In support of the NCI chordoma genetics study, the Contractor shall characterize the function of \textit{PALB2} and \textit{BRCA2} variants identified in NCI chordoma studies.

\section*{4.0. CONTRACT REQUIREMENTS}

The Contractor shall:

4.1 Maintain \textit{PALB2} knock-in mice and monitor potential developmental and cancer phenotypes of homozygous and heterozygous mutant mice.
4.2 Isolate RNA from various tissues from the mice with different \textit{PALB2} genotypes and send RNA to the NCI Project Officer.
4.3 Construct \textit{BRCA2} variant knock-in mouse strain and backcross the founders to C57/BL6 genetic background.
4.4 Monitor potential developmental and cancer phenotypes of homozygous and heterozygous mutant mice.
4.5 Collect various tissues for the mutant mice.
4.6 Derive cells from the mice and characterize their DNA repair efficiency.
4.7 Include appropriate QC controls in all assays.
4.8 Conduct data analysis and reporting.
4.9 Provide technical guidance and troubleshooting to the NCI Technical Point of Contact on the work performed under this procurement.
4.10 Complete analysis on data output and provides all quality control (QC) reports as well as MS docs, any TIFF image, XML files or TXT (raw) files.

\section*{5.0. TYPE OF ORDER}

This is a non-severable firm fixed price purchase order.

\section*{6.0. PERIOD OF PERFORMANCE}

The period of performance will be from date of award for 12 months.

\section*{7.0. PLACE OF PERFORMANCE}

At Contractor Work Site
8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

<table>
<thead>
<tr>
<th>DELIVERABLE</th>
<th>DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS</th>
<th>DUE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Maintain <em>PALB2</em> knock-in mice and monitor potential developmental and cancer phenotypes of homozygous and heterozygous mutant mice.</td>
<td>09/15/20</td>
</tr>
<tr>
<td>4.2, 4.5, 4.6, 4.7</td>
<td>Collect tissues from mice, characterize their DNA repair efficiency, and isolate RNA</td>
<td>09/15/20</td>
</tr>
<tr>
<td>4.3, 4.4</td>
<td>Construct <em>BRCA2</em> variant knock-in mouse strain and monitor potential developmental and cancer phenotypes of homozygous and heterozygous mutant mice.</td>
<td>09/15/20</td>
</tr>
<tr>
<td>4.8, 4.9, 4.10</td>
<td>Conduct data analyses and generate report</td>
<td>09/15/20</td>
</tr>
</tbody>
</table>

All written deliverable products shall be submitted in draft format for review, comment and approval by the NCI Technical Point of Contact (TPC). Final copies of approved drafts shall be delivered to the NCI TPC within five (5) business days after receipt of the Government’s comments.

All written draft and final deliverable products shall be submitted in electronic copy for review and comment. If requested, final deliverable products shall be submitted in hard copy; two (2) final bound copies and one (1) unbound flat final copy suitable for reproduction, in addition to an electronic copy. Other quantities and formats may be submitted after prior approval from the NCI TPC. Electronic copies shall be submitted in Microsoft Office 2007 OR Word format or more recent version, unless prior approval for another format has been obtained from the NCI TPC.

9.0 PAYMENT

Payment shall be made upon delivery, inspection and acceptance of reports/deliverables by the Government. Payment authorization requires submission and approval of invoices to the NCI TPC and NIH OFM, in accordance with the attached payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls; PROMPT PAYMENT (JAN 2017) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:
I INVOICE REQUIREMENTS

A. An invoice is the Contractor’s bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
2. Remit-to address (Name and complete mailing address to send payment).
3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
4. Invoice date.
5. Unique invoice #s for all invoices per vendor regardless of site.
6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the Central Contractor Registration (CCR).
8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN) must be referenced on the invoice. The VIN is the number that appears after the contractor’s name on the face page of the award document.
9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services that match the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.
B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier’s receipt.

C. Mail an original and 1 copy of the itemized invoice to:

    National Institutes of Health
    Office of Financial Management, Commercial Accounts
    2115 East Jefferson Street, Room 4B-432, MSC 8500
    Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the “Consignee” designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

II. INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.
1. A proper invoice was received by the designated billing office.
2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
3. In the case of a final invoice for any balance of funds due the contractor for supplies delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.
IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

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

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

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

10.0 CLAUSES AND PROVISIONS

The following FAR Clauses/Provisions are incorporate as required by the John S. McCain National Defense Authorization Act (NDAA) for FY 2019, Public Law 115-232, Section 889(a)(1)(A).

The following FAR Clauses/Provisions are hereby added in full text.

FAR 52.204-24 - Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment

NOTE: Offerors are required to have an authorized individual self-certify and return attachment from FAR 52.204-24 along with the quote.

FAR 52.204-25 - Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

FAR 52.212-4 - Contract Terms and Conditions -- Commercial Items (October 2018)

FAR 52.212-5 - Contract Terms and Conditions Required to Implement Statutes or Executive Orders -- Commercial.
52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(a), insert the following provision:

REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this provision—

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

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

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

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

(c) Representation. The Offeror represents that—

It [ ] will, [ ] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation.

(d) Disclosures. If the Offeror has responded affirmatively to the representation in paragraph (c) of this provision, the Offeror shall provide the following information as part of the offer—

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

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

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

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

(End of provision)
52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(b), insert the following clause:

PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this clause—

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

Covered telecommunications equipment or services means—

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

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

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

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

Critical technology means—

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

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

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

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

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

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

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

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

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

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

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

(d) **Reporting requirement.**

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

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

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

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