APPENDIX A FLOWDOWN REQUIREMENTS FOR SUBCONTRACT

IN SUPPORT OF

ASTRAZENECA'S MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) AGREEMENT NO.: 2022-402

UNDER PRIME US GOVERNMENT CONTRACT W15QKN-16-9-1002

REVISED DATED 04/08/2024

This appendix applies to any subcontracts in support of this Agreement.

In Appendix A, "Subcontractor" means the "Supplier" and/or "Company", "Subcontract" means this "Agreement.", "Subawardee" means any contractor that has been contracted by Subcontractor to provide goods and services in support of this Agreement, "Government" refers to US Government and/or MCDC.

Subcontractor understands and acknowledges that AstraZeneca is performing Contract No. 2022-402 with Advanced Technology International (ATI) in support of US Government Contract W15QKN-16-9-1002 with Medical CBRN Defense Consortium (MCDC) (the "Contract").

GOVERNMENT SUBCONTRACT

As a Subcontractor to the US Government, AstraZeneca (AZ) must comply with specific provisions, including ensuring that any subcontractors supporting AstraZeneca comply with the terms in the Contract that flow down to subcontractors.

The work required under this Agreement will be performed in support of AstraZeneca's Contract with MCDC/Government. As a Subcontractor under the Contract, Subcontractor must meet certain AstraZeneca's requirements under its agreementwith MCDC/Government. Subcontractor confirms that it is eligible to perform subcontracting work and agrees with the Terms & Conditions/Flowdowns listed in this Appendix. Further, to the extent the Subcontractor must enter into subawards to fulfil requirements of this Agreement or any service hereunder, AZ Contract 2022-402 under US Government Prime Contract W15QKN-16-9-1002. Subcontractor shall take full responsibility to ensure that its subawardees are in full compliance with all applicable Federal procurement laws and regulations and pertinent subcontract requirements, as set in this Appendix.

Subcontractor acknowledges and understands that the Government is a third-party beneficiary to this Agreement and is entitled to the rights and benefits hereunder and may enforce the provisions hereof as if it were a party hereto.

Communication/notification required under this Agreement from/to the Subcontractor to/from Government shall be made through AstraZeneca.

Should any of the terms and conditions contained in Appendix A contradict those elsewhere in the Agreement, or any Statement of Work under the Agreement, then the terms and conditions of Appendix A shall supersede all others.

1. DEFINITIONS

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final agreement for the Government.
"Agreement" refers to this agreement.
"Date of Completion" is the date on which all work is completed, or the date on which the period of performance ends.
"Development" means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service), for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.
"Effective Date" means the date when this Agreement is signed and executed.
"Government" means the U.S. Government and its departments and agencies.
"Government Fiscal Year" means the period commencing on October 1 and ending September 30 of the following calendar year.
"Medical CBRN Defense Consortium (MCDC)" is the consortium formed by industry in response to the Government's expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions.
"Nonprofit Research Institution" means a university or other institution of higher learning, or an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 that is exempt from taxation under Section 501(a) of the Internal Revenue Code, or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.
"Prime Contractor" or "ATI" means Advanced Technology International (ATI)

2. TERMINATION PROVISIONS

AstraZeneca may terminate performance of work under this agreement, in whole or in part, if AstraZeneca determines that a termination is in its best interest. AstraZeneca shall terminate by delivering a Notice of Termination specifying the extent of termination and the effective date. In the event of a termination of the Contract by Government, AstraZeneca shall deliver Notice of Termination to Company promptly. Company shall follow the termination procedures outlined below.

After receipt of a Notice of Termination, and except as directed by AstraZeneca, Supplier shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its suppliers to stop work, as specified in the notice.
(2) Place no further agreements or orders for materials, services, or facilities,
except as necessary to complete the continued portion of the Agreement.
(3) Terminate all orders to the extent they relate to the work terminated.
(4) Assign to AstraZeneca all right, title, and interest under the orders terminated, in which AstraZeneca shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.
(5) AstraZeneca may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this Article. These settlements will be settled to the extent they are settled with the Government. AstraZeneca will not be liable for more than is authorized by the Government.
(6) As directed by AstraZeneca, obtain from the subawardees under the terminated portion of the Agreement, a transfer of title to the following where applicable, and deliver to AstraZeneca.
(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.
(7) Complete performance of any work not terminated, if applicable.
(8) Take any action that may be necessary for the protection and preservation of the property related to this project, that is in the possession of the Subcontractor and in which the Government has or may acquire an interest.

If the Subcontract is terminated when a clinical trial is in progress, Supplier shall follow AstraZeneca's directions on proper close out procedures of such clinical trial (to minimize the impact to the enrolled human subjects).

In the event of a termination of the Agreement, AstraZeneca and Government shall have patent rights and rights in data as described in this Agreement.

3. TERMINATION COSTS

If requested by AstraZeneca, the Subcontractor will provide all necessary data related to the Subcontract, to assist AstraZeneca to negotiate the Settlement of Subcontractor Costs with the Government. The Subcontractor will negotiate in good faith with AstraZeneca for equitable reimbursement for work performed by Subcontractor towards accomplishment of this Agreement.
Subcontractor acknowledges and agrees that only reimbursement expressly authorized and paid by Government to AstraZeneca for the work performed by Subcontractor will be paid to Subcontractor. The Subcontractor acknowledges and agrees that costs incurred by the Subcontractor during a suspension or after termination of a project are not allowable unless the Government expressly authorizes them in either the notices of suspension, termination, or subsequently. Other Subcontractor costs incurred during a suspension or after termination, which are necessary, and not reasonably avoidable, are allowable if:

(a) The costs result from obligations which were properly incurred by the Subcontractor before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended, or the award expired normally at the end of the funding period in which the termination takes effect.

4. CLOSE-OUT

Upon request, AZ shall make prompt payments to the Subcontractor for allowable reimbursable costs under the Agreement being closed out. The Subcontractor shall immediately refund any balance of unobligated (unencumbered) funding that AZ has obligated and that is not authorized to be retained by the Subcontractor for use in the performance of the Agreement. Subcontractor shall submit to AstraZeneca within sixty (60) calendar days after the date of completion of the Agreement, all financial, performance, and other reports required under this Agreement. Quick close-out procedures similar to FAR 42.708, shall be followed and the Subcontractor shall account for any property received from the Government.

5. STOP WORK

AZ may, at any time, by written order to the Subcontractor, require the Subcontractor to stop all, or any part, of the work called for under this Agreement for a period of ninety (90) days after the written order is delivered to the Subcontractor, and for any further period to which the Parties may agree. The order shall be specifically identified as a stop-work order issued under this section. Upon receipt of the order, the Subcontractor shall

immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of ninety (90) days after a stop-work is delivered to the Subcontractor, or within any extension of that period to which the parties shall have agreed, AstraZeneca shall either: (a)Cancel the stop-work order; or (b)Terminate the work covered by the Agreement. If a stop work order issued is canceled, the Subcontractor shall resume work. AZ shall make an equitable adjustment in the delivery schedule or estimated cost/price, or both, commensurate with any adjustment made to AZ by the Government. The Agreement shall be modified, in writing, accordingly, if— (1) The stop-work order results in an increase in the time required for, or in the Subcontractor's cost properly allocable to, the performance of any part of the Agreement; and (2) The Subcontractor must assert its right to an adjustment within twenty (20) days to AstraZeneca after the end of the period of work stoppage. If a stop work order is not canceled and the work covered by the Agreement is terminated in accordance with Article 2, AZ shall work with the Subcontractor to negotiate an equitable reimbursement in accordance with Article 3.

6. ACCOUNTING SYSTEM REQUIREMENTS

Prior to the submission of invoices, the Subcontractor shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The Subcontractor shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

7. FINANCIAL RECORDS AND REPORTS

The Subcontractor shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for funding provided under this Agreement. Subcontractor's relevant financial records are available and subject to examination or audit for a period not to exceed three (3) years after final payment of the Subcontractor's project. AstraZeneca and Government or their designees shall have direct access to sufficient records and information of the Subcontractor to ensure full accountability for all funding under this Agreement. Any audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited Party.

8. CONFIDENTIAL INFORMATION

8.1 DEFINITIONS

"Disclosing Party" means Government, Subcontractor, AZ, or contractual affiliate entity who discloses Confidential Information as contemplated by the subsequent Paragraphs.

"Receiving Party" means Government, Subcontractor, AZ, or contractual affiliate entity who receives Confidential Information disclosed by a Disclosing Party.

"Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret, if such Disclosing Party, within fifteen (15) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information, and indicating that it is confidential or a Trade Secret. "Confidential Information" includes any information and materials considered a Trade Secret by the holder. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic,

or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, regardless of how it is stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Subcontractor understands and agrees that AstraZeneca may provide Confidential Information exchanged under this agreement and any future agreement in support to MCDC/AZ USG contract, to representatives or agents of MCDC and/or U.S. Government in connection with this Agreement. AstraZeneca takes commercially reasonable steps to restrict their disclosure by the MCDC/U.S. Government under applicable public disclosure / transparency laws. AstraZeneca, however, shall have no liability for the MCDC/U.S. Government's release of any Company's Confidential Information.

The Parties agree that all non-public technical data generated as a result of this Agreement with Government is Confidential Information as defined in Section 8.1 and is subject to the provisions of 8,1. For clarity, "non-public technical data" do not include information developed independently of this Agreement.

Except for disclosures to foreign regulatory authorities for emergency use or licensure in that jurisdiction, and except for non-public technical data shared in the ordinary course of business and necessary to commercialize the product, and except for disclosures authorized by export licenses, Subcontractor shall use reasonable measures to prevent non-public technical data related to this Agreement from becoming accessible to any country not a "designated country" as defined by the Trade Agreements Act (TAA) in accordance with FAR 52.225-5.

8.2. EXCHANGE OF INFORMATION

AZ may from time to time, disclose Confidential Information to the Subcontractor. The Subcontractor may from time to time disclose information that is Trade Secret or Confidential Information to the Subcontractor in connection with this Agreement. Neither Party shall be obligated to transfer Confidential Information or Trade Secrets independently developed by the Parties, absent an express written agreement between the Parties providing the terms and conditions for the disclosure.

8.2. AUTHORIZED DISCLOSURE

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties, or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article 10, Patent Rights, and Article 11, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof, as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information, as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media, as well as magnetic and digital storage media.

Subcontractor shall include the requirements set forth in this Article in all Sub-awards entered into after the date of effectiveness of this Agreement. Subcontractor acknowledges that confidential information will not be provided to sub-agreement holders unless or until Article 8 flows down to the relevant sub-agreement, and such entity agrees to be in substantial compliance with this Article.

9. PUBLICATION AND ACADEMIC RIGHTS

Subject to the provisions of Article 8, Confidential Information, Article 9, Publication and Academic Rights, and Article 11, Data Rights, the Government and AstraZeneca, shall have the right to publish or otherwise disclose information and/or data developed by the Subcontractor under this Agreement. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or AstraZeneca.

Publications of any kind regarding the work performed under this Agreement are strictly prohibited. Prior written approval is required to be obtained from AstraZeneca prior to publishing or disclosing any information or data developed under this Agreement. Any publications or public disclosures arising from the performance of the Agreement is subject to AstraZeneca and/or Government's review and approval.

Subject to prior written approval by AstraZeneca, Parties to this Agreement are responsible for assuring that an acknowledgment of Government support will appear in any publication of any material based on or developed under this Agreement, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002**.** The U.S. Government is authorized to reproduce and distribute reprints for Governmental purposes, notwithstanding any copyright notation thereon."

Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project, contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

This requirement shall be a flowdown at all tiers.

Notices. To avoid disclosure of Confidential Information or Trade Secrets and the loss of patent rights as a result of premature public disclosure of patentable information, the Subcontractor agrees to require that any Subawardee that is proposing to publish or disclose such information, to acquire AstraZeneca's written consent.

10. PATENT RIGHTS

A. Definitions

"Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

"Made" when used in relation to any invention, means the conception or first actual reduction to practice of such invention.

It is hereby expressly acknowledged and agreed by Subcontractor that all materials, whether tangible, digital or other form, created, authored or otherwise produced or made by Subcontractor, its employees, agents or sub-awardees, in connection with the provision of services pursuant to this Agreement, including, without limitation, all inventions, creations, expressions, improvements, and all other documentation, whether or not subject to patent or copyright protection, which are first conceived or made or first actually or constructively reduced to practice during the term of this Agreement or within twenty (24) months following the expiration or cancellation hereof, whether based in whole or in part on or derived from information supplied by AstraZeneca, whether preliminary or final, and on whatever media rendered (collectively, the "Work Product"), shall be deemed as **Work Made For Hire**. Such **Work Made For Hire** shall remain the exclusive property of AstraZeneca which shall have the unlimited right to make, have made, use, copy, display in public, reconstruct, repair, modify, reproduce, publish, distribute and sell the Work Product, in whole or in part, or combine the Work Product with other matter, or not use the Work Product at all, as it sees fit.

All Technical Data and Computer Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted). All other Technical Data and Computer Software developed under funding of this Agreement shall be delivered with unlimited rights. Where used in this Agreement, the terms "Limited Rights" and "Unlimited Rights" shall have the meanings set forth in DFARS 252.227-7013.

11. DATA RIGHTS

A. Definitions

(1) "Commercial Computer Software" as used in the Article, is defined in DFARS 252-227-7014(a)(1) (FEB 2014).

(2) “Commercial Computer Software License” means the license terms under which commercial computer software and Data (as defined in this Agreement) is sold or offered for sale, lease or license to the general public.

(3) “Computer Data Base” as used in this Base Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) “Computer Program” as used in this Base Agreement, means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) “Computer Software” as used in this Base Agreement, means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) “Computer Software Documentation” means owner’s manuals, user’s manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) “Data” as used in this Article of the Base Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) “Form, Fit and Function Data” means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) “Government Purpose Rights” means the rights to use, modify, duplicate or disclose the “Data” licensed with such rights within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Government Purpose Rights do not include any right to use, modify, reproduce, perform, release, display, create derivative works from, or disclose that work product for any commercial purpose or to authorize others to do so.

(10) “Limited Rights” as used in this Article, is as defined in DFARS 252.227-7013(a)(14) (FEB 2014).

(11) “Restricted Rights” as used in this Article, is as defined in DFARS 252.227-7014(a)(15) (FEB 2014).

(12) “Specifically Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC, on behalf of the member entity or Subcontractor whose proposal is selected by the Government under a RPP issued under the Agreement.

(13) “Technical Data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited Rights” as used in this Article, is as defined in DFARS 252.227-7013(a)(16).

B. Data

(1) The Data developed and paid for totally by private funds and it is Data to which the Subcontractor retains all rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the Subcontractor under this Agreement which was not developed in the performance of work under that project, and for which the Subcontractor retains all rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the Agreement by Subcontractor. Such Data shall be marked "Category A" and any rights to be provided to the AstraZeneca/Government for such Data under a specific project shall be as identified and incorporated into Agreement.

Disclosure of Data: Subcontractor shall not disclose any data related to this project without AZ written consent.

(2) Disclaimer of Liability: Notwithstanding the above, AstraZeneca shall not be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under the Article, entitled "Confidential Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or is generated by the Government independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the Subcontractor has furnished, or is required to furnish without restriction on disclosure and use.

(3) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend. AstraZeneca and/or MCDC/Government shall have unlimited rights in all unmarked Data.

C. Lower Tier Agreements

The Subcontractor shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

D. Survival Rights

Provisions of this Article shall survive termination of this Agreement.

12. COPYRIGHT

The Subcontractor hereby grants to AZ and/or US Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for Governmental purposes, any copyrighted materials developed under this Agreement, and to authorize others to do so. In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work, and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others

acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the copyright holder. Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use and treated in accordance with such license rights legend markings restricting its use. The Subcontractor is responsible for affixing appropriate markings indicating the rights on all Data delivered under this Agreement.

13. DATA FIRST PRODUCED BY THE GOVERNMENT/ASTRAZENECA

As to Data first produced by the Government/AstraZeneca in carrying out the responsibilities under this Agreement, and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by AstraZeneca and any Subcontractor to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period, such Data may be disclosed and used by the Subcontractor, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government/AstraZeneca for the purposes of this Agreement only.

14. PRIOR TECHNOLOGY

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the Subcontractor, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by the subcontractors of any tier and their respective employees to whom such Data is provided for use under the Agreement. Upon completion of activities under this Agreement, such Data will be disposed of, as requested by AstraZeneca.

(2) Subcontractor Prior Technology: In the event it is necessary for the Subcontractor to furnish AstraZeneca/the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees, that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under the Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by such Government Contractors or contract employees. The Subcontractor shall not be obligated to provide Data that existed prior to, or was developed outside of this Government. Upon completion of activities under Agreement, such Data will be disposed of as requested by the Subcontractor.

(3) Oral and Visual Information: If information which the Subcontractor (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential, is expressly disclosed orally or visually directly to the Government, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to AstraZeneca/the Government five (5) calendar days after such oral or visual disclosure, or AstraZeneca/the Government shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon AstraZeneca request, additional detailed

information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor AstraZeneca shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under the Article entitled "Confidential Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or AstraZeneca or is generated by the Government or AstraZeneca independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the Subcontractor has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

The Subcontractor shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Provisions of this Article shall survive termination of this Agreement.

15. EXPORT CONTROL

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR).

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act, and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- This document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401, et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown. The Subcontractor shall include this Article, suitably modified, to identify all Parties, in all lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

16. GOVERNMENT FURNISHED PROPERTY/TITLE TO PROPERTY

No significant items of property are expected to be acquired under this Agreement by the Subcontractor. Title to any item of property valued $0.00 that is acquired by the Subcontractor, in performance of the project issued to the Subcontractor under this Agreement, shall vest in the Subcontractor upon acquisition with no further obligation of the Parties. Should any item of property with an acquisition value greater than $0.00 be required, the Subcontractor shall obtain prior written approval from AZ. That Subcontractor shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired

pursuant to this Article shall not be considered as in exchange for services in performance of the project but shall be considered a Government contribution to the project.

The Parties do not anticipate the use of Government-Furnished Property (GFP), Government-Furnished Equipment (GFE), or Government-Furnished Material (GFM) under this SOW. Should the Government provide GFP, GFE, or GFM, or any other such form of support, it would be governed by the applicable provisions of the Agreement.

17. CIVIL RIGHTS ACT

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each Subcontractor to assure the Subcontractor has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

18. ANTITRUST

Subcontractor agrees to comply with all applicable U.S. laws, including U.S. antitrust laws.

19. SECURITY & OPSEC

Subcontractor shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, when applicable.

Subcontractor shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

This Agreement is Unclassified, however work performed under it may involve access to Classified Information, including but not limited to, information classified as Controlled Unclassified Information (CUI), Confidential, Secret, or Top Secret. As such, DoD Manual 5200.01 (DoD Information Security Program: Protection of Classified Information) shall apply and all appropriate measures shall be followed. Subcontractor shall also comply with Distribution Statements, as mandated by DoDI 5230.24 (Distribution Statements on Technical Documents). If a project involves a classified or CUI effort, the below listed Department of Defense Directives, FAR/DFARS Clauses, and supplemental clauses/guidance will be incorporated into the Agreement by reference with the same force and effect as if they were given in full text.

Specific applicable policies, instructions, and regulations will be identified in each project. If any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.

a. DoDM 5200.01, DoD Information Security Program, 24 Feb 12, Volumes 1-4
b. DoD 5200.2-R, Personnel Security Program, Jan 87
c. DoDD 5220.22, National Industrial Security Program, 28 Feb 06

d. DoD 5400.7-R, DoD Freedom of Information Act, Sept 98
e. DoDI 2000.12, DoD Antiterrorism Program, 01 Mar 12
f. FAR Clause 4.402, Safeguarding Classified Information Within Industry
g. FAR Clause 52.204-2, Security Requirements, Aug 1996

Classification guidance for requirement: "The security level for this agreement is UNCLASSIFIED."

Mandatory Controlled Unclassified Information (CUI) Training.

For all agreements awarded, and in accordance with Part 2002 of Title 32, CFR, CUI requires safeguarding or dissemination controls identified in a law, regulation, or government-wide policy for information that does not meet the requirements for classification in accordance with E.O. 13526. The Subcontractor shall follow the guidance for Controlled Unclassified Information, DoDI 5200.48 to implement policy, assign responsibilities, and provide procedures for the designation, marking, protection, and dissemination of controlled unclassified information (CUI). Pursuant to DoDI 5200.48, Section 3, contractual requirements, every individual at every level, including DoD civilian and military personnel as well as contractors providing support to the DoD, shall comply with the requirements in Paragraph 3.6.f. Subcontractor shall require its personnel performing this Statement of Work to take initial and annual refresher CUI training. DoD Mandatory CUI mandatory training can be found at the following website: https://securityawareness.usalearning.gov/cui/index.html. Training is required within 15 calendar days after project award effective date or effective date of incorporation of this requirement into the project award, whichever is applicable. The Subcontractor shall submit certificates of completion for each affected Subcontractor employee within 15 calendar days after completion of training by all subcontractor personnel. The Subcontractor shall submit certificates of completion for each affected subcontractor employee as an appendix to the monthly status report.

20. QUALITY OVERSIGHT

Subcontractor agrees to provide Government or its designated representative the opportunity to accompany AZ on all quality audits of its subcontractors. The Government's participation in any routine quality audit of its subcontractors shall be limited to a silent observation role and the Government's participation in any of for-cause audits of its subcontractors shall not be limited to a silent observation role, but the Government or designated representative(s) shall cooperate with its subcontractors to minimize redundancy and promote efficiency of the audit.

21. PRODUCTION OF HUMAN SUBJECTS

The Subcontractor agrees that the rights and welfare of human subjects involved in research under this project agreement shall be protected in accordance with 45 CFR Part 46 and with the Subcontractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP). The Subcontractor further agrees to provide AstraZeneca with the 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.

The Subcontractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Subcontractor retains the right to control and direct the performance of all work under this Agreement. Nothing in this Agreement shall be deemed to constitute the Subcontractor or any contractor, agent or employee of AZ, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Subcontractor agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto,

whether requiring professional judgment or otherwise, as an independent entity. Non-compliance with this Clause may result in withholding of funds and/or the termination of the Agreement.

22. CARE OF LIVE VERTEBRATE ANIMALS

Before undertaking performance of any contract or project agreement involving animal related activities, the Subcontractor shall register with the Secretary of Agriculture of the United States. The Subcontractor shall furnish evidence of compliance to AZ.

The Subcontractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture in accordance with applicable laws and standards, or from a source that is exempt from licensing under those sections. The Subcontractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this Agreement will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture. In case of conflict between standards, the more stringent standard shall be used.

Non-compliance with this Clause may result in withholding of funds and/or the termination of the Agreement.

Note: The Subcontractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737. (E-mail: ace@aphis.usda.gov; website: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare).
Office of Laboratory Animal Welfare Number +1 (301) 851-3751.

23. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: https://olaw.nih.gov/policieslaws/phs-policy.htm

24. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW), https://olaw.nih.gov/. An essential requirement of the PHS Policy, https://olaw.nih.gov/policies-laws/phs-policy.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service. If the Subcontractor does not have an assurance and will be utilizing a lower tier agreement to perform the animal work, then Subcontractor must have an Inter-Institutional Assurance in place to allow the Subcontractor to utilize the assurance of the lower tier subcontractor to meet the HHS requirements for assurance.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for

the Care and Use of Laboratory Animals, https://nap.nationalacademies.org/catalog/12910/guide-for-the-care-and-useof-laboratory-animals-eighth and that they comply with the regulations (9 CFR, Subchapter A) https://www.nal.usda.gov/animal-health-and-welfare issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) https://www.aaalac.org/ is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies, https://www.fass.org/.

25. APPROVAL OF REQUIRED ASSURANCE BY LAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Subcontractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Subcontractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Subcontractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at https://olaw.nih.gov/policies-laws/phs-policy.htm

26. SAFETY

The Subcontractor shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project. At a minimum, the Subcontractor shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The Subcontractor shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage, may be involved; identifying a potential hazard requiring corrective action. The Subcontractor shall prepare the report for each incident, in accordance with DI-SAFT-81563.

Material Safety Data Sheets (MSDS): The Subcontractor shall prepare and maintain MSDS for all materials used and generated in support of this project.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, executive orders, treaties, and agreements. The Subcontractor shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under the project.

Hazardous Waste Report: The Subcontractor shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the project. The Subcontractor shall submit a Hazardous Waste Report, in accordance with DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The Subcontractor shall dispose of all residual and scrap materials generated under the project, including high explosives. The Subcontractor shall specify the anticipated quantities, methods, and disposal costs.

27. INSPECTION/ACCEPTANCE

A. Inspection: Subcontractor agrees that AstraZeneca and/or Government have the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. AstraZeneca and/or the Government may also inspect the premises of the Subcontractor or any of its Sub-awardees engaged after the Effective Date, with seven (7) days advance notice to the Subcontractor or any such Sub- awardee. The scope and duration of any such inspection will be mutually agreed between the Parties in writing in advance,such agreement not to be unreasonably withheld. AstraZeneca and/or the Government shall perform inspections and tests in a manner that will not unduly delay the work and will be subject to the Subcontractor's or its subawardees', as applicable, policies and procedures regarding security and facility access at all times while on the premises. If AstraZeneca and/or the Government perform any inspection or test on the premises of the Subcontractor or its Sub-awardee, the Subcontractor shall furnish, and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, AstraZeneca and/or the Government shall bear the expense of such inspections or tests made at other than the Subcontractor's or its Sub-awardee's premises.

B. Acceptance: Subcontractor agrees that AstraZeneca and/or MCDC/Government shall inspect/accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. AstraZeneca and/or Government failure to inspect and accept or reject the work shall not relieve the Subcontractor from responsibility, nor impose liability on AstraZeneca for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. AstraZeneca and/or Government have the right to reject nonconforming work. Inspection/Acceptance of the supply deliverables should not exceed 90 days after completion.

28. LIABILITY OF THE PARTIES

Except as expressly provided herein, no Party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to, (1) any research conducted under this Agreement, or (2) any invention conceived and/or reduced to practice under Agreement, or (3) any other intellectual property developed under this Agreement, and each Party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct. Notwithstanding the foregoing, this waiver of liability shall not be applicable to: (1) Claims between the AstraZeneca and the Subcontractor regarding a material breach, noncompliance, or nonpayment of funds; (2) Claims for damage caused by willful misconduct; and (3) Intellectual property claims.

29. DAMAGES

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

30. SEVERABILITY

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

31. FORCE MAJEURE

No failure or omission by the Subcontractor in the performance of any obligation of this Agreement, shall be deemed a breach of this Agreement, or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: Acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion, and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

32. REGULATORY AFFAIRS

Development and production of medical products and processes fall under the purview of the FDA and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. project awards under this Agreement that involve work in support of or related to FDA regulatory approval, will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this agreement shall be done ethically and in accordance with all applicable laws, directives, and regulations.

33. REGULATORY COMPLIANCE

GCP Compliance (as applicable). Subcontractor shall maintain capabilities required to ensure full compliance with current Good Clinical Practices (GCP) when conducting clinical testing.

cGMP Compliance (as applicable) Subcontractor shall maintain capabilities required to ensure full compliance with current Good Manufacturing Practices (cGMP) when manufacturing and testing products intended to be investigated or used in humans.

GLP Compliance (as applicable) Subcontractor shall maintain capabilities required to ensure full compliance with Good Laboratory Practices (GLP) when conducting nonclinical studies which require GLPs.

The Subcontractor shall flow down the requirements of Clause 33 to any sub-contractors.

34. RADIOACTIVE MATERIALS

Subcontractor shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

35. RECOMBINANT DNA

The Subcontractor shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/ (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

36. REQUIRED COMPLIANCE FOR USE OF LABORABORY ANIMALS

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the Subcontractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the U.S. Army Medical Research and Development Command, Animal Care and Use Review Office (ACURO). The Subcontractor shall receive written approval to begin research under the applicable protocol proposed for an Agreement from the U.S. Army Medical Research and Development Command, Animal Care and Use Review Office, ACURO, under separate letter to the SUBCONTRACTOR and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this Article may result in the termination of award. Information is provided at the following website https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro. The Subcontractor will conduct advanced development/pivotal studies, including human safety studiehums, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies, as defined by FDA guidance (21 CFR Parts 210-211). The Subcontractor shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

37. REQUIRED COMPLIANCE FOR USE OF HUMAN SUBJECTS

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Development Command's Office of Research Protections, Human Research Protection Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award, will be issued from the U.S. Army Medical Research and Development Command, HRPO, under separate letter, to

the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this Article may result in withholding of funds and/or the termination of the award. Information is provided at the following website: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo. The Subcontractor shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

38. REQUIRED COMPLIANCE FOR USE OF HUMAN ANATOMICAL SUBSTANCES

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Development Command's Office of Research Protections, Human Research Protections Office, HRPO, approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award, will be issued from the U.S. Army Medical Research and Development Command, HRPO, under separate letter, to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this Article may result in withholding of funds and/or the termination of the award. Information is provided at the following web site: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo.

39. COMPLIANCE WITH CURRENT GOOD MANUFACTURING PROCESSES (cGMP)

Manufacturing Standards, as appropriate for the level of prototype material used for clinical trials, pivotal non-clinical studies, consistency lots, and other uses, as defined in regulatory plans, should be compliant with current cGMP, as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the Subcontractor fails to comply with cGMP in the manufacturing, processing and packaging 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 Subcontractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

40. REGISTRATION WITH SELECT AGENT PROGRAM

Where required, Subcontractors performing studies and tasks using select biological agent or toxins, should be registered with the program 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, 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. Listings of 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/. The Subcontractor shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

41. DUTY-FREE ENTRY

(a) Definitions. As used in this Article –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.

(2) "Customs territory of the United States," means the 50 States, the District of Columbia, and Puerto Rico.

(3) "Eligible product," means –

(i) "Designated country end product," as defined in the Trade Agreements clause;

(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product," a

"Moroccan end product," a "Panamanian end product," or a "Peruvian end product," as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program clause; or

(iii) "Canadian end product," as defined in Alternate I of the Buy American Act – Free Trade Agreements –

Balance of Payments Program clause

(iv) "Free Trade Agreement country end product," other than a "Bahrainian end product," "Korean end product," "Moroccan end product," "Panamanian end product," or "Peruvian end product," as defined in of the Buy American—Free Trade Agreements—Balance of Payments Program clause.

(4) "Qualifying country" and "qualifying country end product," have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program clause.

(b) Except as provided in Paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of the applicable subcontract, the price of this Agreement shall not include any amount for duty on-

(1) End items that are eligible products or qualifying country end products;

(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated into U.S – made end products to be delivered under an Agreement; or

(3) Other supplies for which the Subcontractor estimates that duty will exceed $200 per shipment into the customs

territory of the Unites States.

(c) The Subcontractor shall –

(1) Claim duty-free entry only for supplies that the Subcontractor intends to deliver under this Agreement, either as end items or components of end items; and

(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –

(i) Scrap or salvage; or

(ii) Competitive sale made

(d) Except as the Subcontractor may otherwise agree, AZ will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –

(1) For which no duty is included in the Agreement price in accordance with Paragraph (b) of this clause; and

(2) For which shipping documents bear the notation specified in Paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –

(1) Consign the shipments to the appropriate –

(i) Military department in care of the Subcontractor, including the Subcontractor's delivery address; or

(ii) Military installation; and

(2) Include the following information:

(i) Prime agreement number and, if applicable, delivery order number.

(ii) Number of the subcontract for foreign supplies, if applicable.

(iii) Identification of the carrier.

(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of

Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 201 Varick Street, Room 905C, New York, New York, 10014, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty-free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the Subcontractor shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)

(vi) Estimated value in U.S. dollars.

(vii) Activity address number of the contract administration office administering the prime agreement, e.g., for DCMA Dayton, S3605A.

(f) Preparation of customs forms.

(1)(i) Except for shipments consigned to a military installation, the Subcontractor shall –

(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this agreement; and

(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.

(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.

(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the Subcontractor shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The Subcontractor shall –

(1) Prepare (if the Subcontractor is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two (2) of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;

(2) Consign the shipment as specified in Paragraph (e) of this clause; and

(3) Mark on the exterior of all packages –

(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and

(ii) The activity address number of the contract administration office administering the prime agreement.

(h) The Subcontractor shall notify AZ in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to AZ for incorporation in end items. The Subcontractor shall furnish the notice to AZ immediately upon award to the supplier, and shall include in the notice –

(1) The Subcontractor's name, address, and Commercial and Government Entity (CAGE) code;

(2) Prime agreement number and Agreement number;

(3) Total dollar value of the prime agreement or Agreement number;

(4) Date of the last scheduled delivery under the Agreement number;

(5) Foreign supplier's name and address;

(6) Number of the subcontract for foreign supplies;

(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the Subcontractor will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –

(i) Scrap of salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer;

(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this agreement if –

(1) The supplies are identical in nature to supplies purchased by the Subcontractor in connection with its commercial business; and
(2) It is not economical or feasible to account for such supplies, so as to ensure that the amount of the supplies
for which duty-free entry is claimed does not exceed the amount purchased in connection with this agreement.

(j) The Subcontractor shall –

(1) Insert the substance of this clause, including this Paragraph (j), in all subcontracts for –

(i) Qualifying country components; or
(ii) Non-qualifying country components for which the Subcontractor estimates that duty will exceed $200 per unit;

(2) Require subcontractors to include the number of this agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
(3) Include in applicable subcontracts –

(i) The name and address of the ACO for this agreement;
(ii) The name, address, and activity address number of the contract administration office specified in this
agreement; and
(iii) The information required by Paragraphs (h)(1), (2), and (3) of this clause.

42. PUBLIC READINESS AND EMERGENCY PREPARDNESS ACT (PREP Act)

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

43. GENERAL

No waiver of any rights shall be effective unless assented to in writing by the Party to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

The headings and subheadings of the sections of this Agreement are intended for convenience of reference only, and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

44. PROHIBITION ON THE USE OF CERTAIN TELECOMMUNICATIONS AND VIDEO SUVEILLANCE SERVICES OR EQUIPMENT

This Article is to ensure compliance with Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232).

A. Definitions

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.*, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (*e.g.*, fiber optic, coaxial cable, Ethernet).

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

Covered telecommunications equipment or services means–

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

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

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

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

Critical technology means–

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

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

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

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

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

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

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

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

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

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

B. Prohibition

(1) The Subcontractor is prohibited from providing 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 the Subcontractor is providing (i) a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or (ii) 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, or the covered telecommunication equipment or services. A waiver, for a period not exceeding August 13, 2021, may be requested.

(2) The Subcontractor acknowledges and accepts that AstraZeneca is prohibited from entering into a new project agreement, exercising an option under an existing project, bilaterally modifying the project agreement to extend the term of a project, executing an additional phase, incrementally funding an existing project with the Subcontractor or with an entity that uses 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 (b)(1) of this article applies, regardless of whether that use is in performance of work under a Federal contract or agreement.

C. Certification (to be completed upon Agreements Officer Request)

The Subcontractor shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services."

Based on that review:

1. □ The Subcontractor certifies that it does □ does not □ provide covered telecommunications equipment or services as a part of its offered products or services in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument.

2. If the Subcontractor does provide covered telecommunications equipment or services as a part of its offered products or services in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument as described in paragraph (c)(1), the Subcontractor certifies that it will □ will not □ provide covered telecommunications equipment or services in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation. If the Subcontractor will provide covered telecommunications equipment or services in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation (C)(2), the Subcontractor shall provide the additional disclosure information required at paragraph (D)(1) of this Article.

3. The Subcontractor certifies, after conducting a reasonable inquiry, for purposes of this certification, that it does □ does not □ use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. If the Subcontractor does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services as described under this paragraph (C)(3), the Subcontractor shall provide the additional disclosure information required at paragraph (D)(2) of this Article.

D. Disclosures

(1) Disclosure for the certification in paragraph (C)(2) of this Article. If the Subcontractor does provide covered telecommunications equipment or services in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument in in paragraph (C)(2) of this provision, the Subcontractor shall provide the following information:

(i) For covered equipment—

a. The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, Commercial and Government Entity (CAGE) code, and whether the entity was the Original Equipment Manufacturer (OEM) or a distributor, if known);
b. A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
c. Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(ii) For covered services—

a. If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
b. If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(2) If the Subcontractor does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services in in paragraph (C)(3) of this Article, the Subcontractor shall provide the following information:

(i) For covered equipment—

a. 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);
b. A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
c. Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

(ii) For covered services—

a. If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
b. If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

E. Reporting Requirement

(1) In the event the Subcontractor 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 agreement performance, or the Subcontractor is notified of such by a subcontractor at any tier or by any other source, the Subcontractor shall report the information in paragraph (E)(2) of this Article to the Agreements Officer and to the Department of Defense website at https://dibnet.dod.mil. The Subcontractor must notify the CMF that a report has been made.

(2) The Subcontractor shall report the following information pursuant to paragraph (E)(1) of this clause:

(i) Within one (1) business day from the date of such identification or notification: the agreement number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier 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 ten (10) business days of submitting the information in paragraph (E)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Subcontractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or

services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

F. Subcontracts/Suppliers

The Subcontractor shall insert the substance of this article, including this paragraph (F) and excluding paragraph (B)(2), in all subcontracts, subawards and other contractual instruments, including subcontracts for the acquisition of commercial items.

Hazardous Waste Report - DI-MGMT-80899

DATA ITEM DESCRIPTION	Form Approved OMB No. 0704-0188

2. TITLE	1. IDENTIFICATION NUMBER
HAZARDOUS WASTE (HW) REPORT	DI-MGMT-80899

3. DESCRIPTION/PURPOSE

3.1 This report identifies the specific type and amount of hazardous waste being generated. It is used by the government to determine if hazardous waste is being effectively managed.

4. APPROVAL DATE (YYMMDD)	5. OFFICE OF PRIMARY RESPONSIBILITY (OPR)	6a. DTIC REQUIRED	6b. GIDEP REQUIRED
890907	F/AFSPACECOM-3SSW/XREC		

7. APPLICATION/INTERRELATIONSHIP

7.1 This data item description (DID) contains the format and content preparation instructions for the data product generated by the specific and discrete task requirement as delineated in the contract.

7.2 Applicable to Operations and Maintenance contracts that generate or manage hazardous waste.

8. APPROVAL LIMITATION	9a. APPLICABLE FORMS	9b. AMSC NUMBER
		F4813

10. PREPARATION INSTRUCTIONS

10.1 Format. The report shall be in a contractor devised horizontal format.

10.2 Content. The HW Report shall contain the installation name, office, and phone number of the person preparing the report, date prepared, and the data shown below. The date shall be entered using the following format: yy/mm/dd.

a. Responsible Tenant/Unit. The name of the unit, department or command responsible for generating the hazardous waste.

b. Waste Description: Identification and description or the waste generated.

c. Environmental Protection Agency (EPA) Waste Number. Number assigned by EPA to the waste.

d. Department of Transportation (DOT) Shipping Number. Number assigned by DOT to the waste.

e. Hazard. The known hazard of the hazardous waste. Is it toxic, corrosive, reactive or ignitable?

f. Quantity. The quantity of hazardous waste generated monthly (kilograms, pounds or gallons).

g. Location. The location where the hazardous waste is generated.

h. Quantity Stored. The average quantity stored at one time.

i. Average Storage. The average storage time.

j. Disposal. The current removal/disposal practices, Defense Reutilization and Marketing Office, etc.

k. Disposal Cost. Cost of Disposal.

11. DISTRIBUTION STATEMENT

DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited.