AGREEMENT #: HR0011-18-3-0001 FLOWDOWN REQUIREMENTS FOR SUBCONTRACTS

(Appendix A)

This appendix applies to any subcontracts in support to AstraZeneca prime agreement with DARPA HR0011-18-3-0001.

In Appendix A, "Subcontractor" means the "Supplier" and "Subcontract" means this "Agreement." Subcontractor understands and acknowledges that MedImmune/AstraZeneca (AstraZeneca) is performing a Technology Investment Agreement (TIA) with The Defense Advanced Research Projects Agency (DARPA) of the United States Government (Government), Agreement # HR0011-18-0001

GOVERNMENT SUBCONTRACT

As a prime contractor to DARPA, AstraZeneca must comply with specific provisions of the Agreement, including ensuring that any subcontractors supporting AstraZeneca comply with the terms in the Agreement that flow down to subcontractors.

The work required under this Agreement will be performed in support of AstraZeneca's TIA with DARPA. As a Subcontractor under the TIA, Subcontractor must meet certain AstraZeneca's requirements under its prime agreement with DARPA. Subcontractor confirms that it is eligible to perform subcontracting work under a government contract and agrees with the Conditions/Flowdowns listed in this Appendix. Further, to the extent the Subcontractor must enter into subcontracts to fulfil requirements of this Agreement or any service hereunder HR0011-18-0001 Subcontractor shall take full responsibility to ensure that its subcontracts are in full compliance with all applicable Federal procurement laws and regulations and pertinent subcontract requirements, as set in this Appendix.

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.

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.

CONFIDENTIAL INFORMATION

Subcontractor further understands and agrees that AstraZeneca may provide Confidential Information in regard to this Agreement (including information exchanged pursuant to an existing confidentiality or nondisclosure agreement) to representatives or agents of the U.S. Government in connection with AstraZeneca's prime Agreement HR0011-18-0001. AstraZeneca takes commercially reasonable steps to restrict their disclosure by the U.S. Government under applicable public disclosure / transparency laws. AstraZeneca, however, shall have no liability for the U.S. Government's release of any Subcontractor Confidential Information.

COMMUNICATION

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

PATENT RIGHTS *(Applicable if the subcontract is for experimental, developmental, or research work under the Program.)*

A. Allocation of Principal Rights

1. Unless the Subcontractor shall have notified ASTRAZENECA, in accordance with subparagraph B.2 below, that the Subcontractor does not intend to retain title, in which case title shall vest with AstraZeneca or the Government the Subcontractor shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article.

2. With respect to any Subject Invention developed under this Agreement, in which Subcontractor retains title, ASTRAZENECA and DARPA shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.

B. Subject Invention Disclosure, Election of Title, and Filing of Patent Application

1. Subcontractor shall disclose each Subject Invention to ASTRAZENECA within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to ASTRAZENECA shall be in the form of a written report and shall identify the Agreement and circumstances under which the Subject Invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention. The disclosure shall also identify any publication, sale, or public use of the Subject Invention and whether a manuscript describing the Subject Invention has been submitted and/or accepted for publication at the time of disclosure.

2. If the Subcontractor determines that it does not intend to retain title to any such Subject Invention, the Subcontractor shall notify ASTRAZENECA, in writing, within eight (8) months of disclosure to ASTRAZENECA. However, in any case where publication, sale, or public use will be made, Subcontractor shall notify ASTRAZENECA no less than sixty (60) days prior to any such publication, sale, or public use.

3. The Subcontractor shall file its initial patent application on a Subject Invention to which it elects to retain title consistent with its commercialization strategy for any potential product launch or within one year of disclosure of its intellectual property in, for example, a publication, public use, sale or offer for sale, or otherwise making it available to the public. The Subcontractor may elect to file patent applications in additional countries (including the European Patent Office or pursuant to the Patent Cooperation Treaty), within either (12) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. The Subcontractor shall notify ASTRAZENECA of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period, or extension thereof, required by the relevant patent office.

5. Requests for extension of the time for disclosure election, and filing under this Article may be granted at ASTRAZENECA's discretion after considering the circumstances of the Subcontractor and the overall effect of the extension.

6. The Subcontractor shall submit to ASTRAZENECA a listing of Subject Inventions as a part of the quarterly reports. At the completion of the Agreement, the Subcontractor shall submit a comprehensive listing of all Subject Inventions identified during the course of the Agreement and the current status of each.

C. Conditions When the Government May Obtain Title

Upon ASTRAZENECA's written request, the Subcontractor shall convey title to any Subject Invention to ASTRAZENECA under any of the following conditions:

1. If the Subcontractor fails to disclose or elects not to retain title to the Subject Invention within the times specified in Paragraph B of this Article, provided Subcontractor did not intentionally fail to disclose the Subject Invention to ASTRAZENECA and upon actually becoming aware of such failure does not remedy the failure within sixty (60) calendar days; however, ASTRAZENECA may only request title within sixty (60) calendar days after learning of the failure of the Subcontractor to disclose or elect within the specified times;

2. In those countries in which the Subcontractor fails to file patent applications for a Subject Invention within the times specified in paragraph B of this Article, provided if such failure to file is consistent with its commercialization strategy for any potential product launch, but prior to its receipt of the written request by ASTRAZENECA, Subcontractor is not required to convey title; or

3. In any country in which the Subcontractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

D. Minimum Rights to the Subcontractor and Protection of the Subcontractor's Right to File

1. Subcontractor shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which ASTRAZENECA and/or the Government obtains title, except if the Subcontractor fails to disclose the Subject Invention within the times specified in paragraph B of this Article; provided Subcontractor did not intentionally fail to disclose the Subject Invention to ASTRAZENECA and upon actually becoming aware of such failure does not remedy the failure within sixty (60) calendar days. The Subcontractor's license extends to its subsidiaries and affiliates, if any, and includes the right to grant licenses of the same scope to the extent that the Subcontractor was legally obligated to do so at the time the Agreement was awarded. The license is transferable only with the approval of ASTRAZENECA, except when transferred to the successor of that part of the business to which the Subject Invention pertains. ASTRAZENECA approval for license transfer shall not be unreasonably withheld.

2. The Subcontractor's domestic license may be revoked or modified by ASTRAZENECA or DARPA to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the Subcontractor has achieved practical application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of ASTRAZENECA to the extent the Subcontractor, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country. For clarity, the licenses referenced under this subparagraph D.2, are the licenses granted to Subcontractor under subparagraph D.1 of this article.

3. Before revocation or modification of the license, ASTRAZENECA shall furnish the Subcontractor a written notice of its intention to revoke or modify the license, and the Subcontractor shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified. ASTRAZENECA shall consider in good faith Subcontractor's notice.

E. Action to Protect the Government's Interest

1. The Subcontractor agrees to execute or to have executed and promptly deliver to ASTRAZENECA all instruments necessary to (i) establish or confirm the rights the ASTRAZENECA and/or Government has throughout the world in those Subject Inventions to which the Subcontractor elects to retain title, and (ii) convey title to ASTRAZENECA or DARPA, when requested under paragraph C of this Article and to reasonably cooperate where necessary, at the ASTRAZENECA and/or Governments sole and absolute expense, to enable the ASTRAZENECA and/or Government to file and prosecute patent applications throughout the world to Subject Inventions owned by the ASTRAZENECA and/or Government.

2. The Subcontractor agrees, consistent with its policies and procedures, to facilitate disclosure of Subject Invention developed by its employees in writing to personnel identified as responsible for the administration of patent matters and in a format to facilitate Subcontractor's compliance with the disclosure provisions of paragraph B of this Article. The Subcontractor shall, consistent with its policies and procedures, instruct employees on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

3. The Subcontractor shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement No. HR0011-18-3-0001, awarded by DARPA. The Government has certain rights in the invention."

F. Lower Tier Agreements

The Subcontractor shall include this Article, suitably modified, in all subcontracts for experimental, developmental, or research work under the Program.

G. Reporting on Utilization of Subject Inventions

1. Subcontractor agrees to submit, during the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Subcontractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Subcontractor, and such other data and information as the agency may reasonably specify. Subcontractor also agrees to provide additional reports as may be requested by ASTRAZENECA in connection with any march-in proceedings undertaken by ASTRAZENECA or Government in accordance with Paragraph I of this Article. ASTRAZENECA agrees it shall not disclose such information to persons outside the Government without permission of the Subcontractor, unless required by law and, in which case, ASTRAZENECA shall notify Subcontractor and reasonably cooperate with Subcontractor so Subcontractor may take whatever action necessary to seek confidential treatment as appropriate.

2. All required reporting shall be submitted to ASTRAZENECA.

H. Preference for American Industry

Notwithstanding any other provision of this clause, the Subcontractor agrees a license granting rights to use or sell any Subject Invention in the United States shall be granted only to a licensee who agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement may be waived by ASTRAZENECA or DARPA upon a showing by the Subcontractor that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

I. March-in Rights

The Subcontractor agrees that, with respect to any Subject Invention in which it has retained title, ASTRAZENECA has the right to require the Subcontractor, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Subcontractor, assignee, or exclusive licensee refuses such a request, ASTRAZENECA or DARPA has the right to grant such a license itself if ASTRAZENECA or DARPA determines that:

1. Such action is necessary because the Subcontractor or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Subcontractor, assignee, or their licensees;

3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Subcontractor, assignee, or licensees; or

4. Such action is necessary because the agreement required by paragraph (H) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such Agreement.

DATA RIGHTS *(Applicable if the subcontract is for experimental, developmental, or research work under the Program.)*

A. Allocation of Principal Rights

1. The Parties agree that in consideration for Government funding, the Subcontractor intends to reduce to practical application items, components and processes developed under this Agreement.

2. With respect to Data developed or generated under this Agreement related to the Program, the Government shall receive Government Purpose Rights, as defined in Article I, paragraph B, and consistent with the Department of Defense Federal Acquistion Regulation (DFARS) 227.7103-7.

3. With respect to Data delivered pursuant to Attachment 2 under the Agreement, the Government shall receive Government Purpose Rights subject to the obligations under subparagraph A.2 of this Article. Notwithstanding the provision in A.4, the Subcontractor agrees, with respect to Data generated or developed under this Agreement, the ASTRAZENECA or Government may, within two (2)

years after completion or termination of this Agreement, require delivery of a copy of Data developed or generated under this Agreement and receive Government Purpose Rights.

4. March-In Rights

(a) In the event the Government chooses to exercise its March-in Rights, as defined in Article "Patent Rights" Section I of this Agreement, the Subcontractor agrees, upon written request from the ASTRAZENECA, to deliver at no additional cost to the ASTRAZENECA, all copies of Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. ASTRAZENECA and Government shall retain Unlimited Rights, as defined in Article I, Section B of this Agreement, to this delivered Data.

(b) To facilitate any potential deliveries, the Subcontractor agrees to retain and maintain in good condition until after completion or termination of this Agreement, all Data necessary to achieve practical application of any Subject Invention developed under this Agreement.

B. Marking of Data

Pursuant to paragraph A above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement HR0011-18-3-0001 between the Government and ASTRAZENECA .

C. Lower Tier Agreements

The Subcontractor shall include this Article, suitably modified to identify the Parties, in all subcontracts for experimental, developmental, or research work under the Program.

FOREIGN ACCESS TO TECHNOLOGY *(Applicable if the subcontract is for experimental, developmental, or research work under the Program.)*

This Article shall remain in effect during the term of the Agreement and for two (2) years thereafter.

A. General

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national defense, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulation (22 CFR pt. 121 et seq.), the National Industrial Security Operating Manual (NIPSOM) (DoD 5220.22-M) and the Department of Commerce Export Regulation (15 CFR pt. 770 et seq.)

B. Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions

1. In order to promote the national security interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs C.2, C.3, and C.4 below shall apply to any transfer of Technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:

(a) sales of products or components, or

(b) licenses of software or documentation related to sales of products or components, or

(c) transfer to foreign subsidiaries of the Performer for purposes related to this Agreement, or

(d) transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. Subcontractor shall provide timely notice to ASTRAZENECA of any proposed transfers from the Subcontractor of Technology developed under this Agreement to Foreign Firms or Institutions. If ASTRAZENECA or DARPA determines that the transfer may have adverse consequences to the national security interests of the United States, the Subcontractor, its vendors, ASTRAZENECA and DARPA shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to the Subcontractor.

3. In any event, the Subcontractor shall provide written notice to the ASTRAZENECA of any proposed transfer to a foreign firm or institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. No transfer shall take place until a decision is rendered by ASTRAZENECA.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by ASTRAZENECA or DARPA takes place, the Subcontractor shall (a) refund to ASTRAZENECA funds paid for the development of the Technology and (b) the ASTRAZENECA and Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for ASTRAZENECA, Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the ASTRAZENECA, the Subcontractor shall provide written confirmation of such licenses.

C. Lower Tier Agreements

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

ANIMAL STUDIES *(Applicable if subcontract involves the use of animals)*

Research that involves the use of animals shall be administratively reviewed by a DoD veterinarian prior to the Subcontractor initiating any animal research. The Subcontractor is not to begin any research or purchase any materials, equipment, etc. that would involve animal use until the protocol has been approved.

Once the Subcontractor receives its copy of the Protocol Approval Letter from ASTRAZENECA or DoD Regulatory Office, the Subcontractor is approved to proceed with the effort involving animal use, in accordance with guidance in the Protocol Approval Letter. The Protocol Approval Letter shall be incorporated to this agreement as an attachment.

ANIMAL WELFARE *(Applicable if subcontracts involve research of live vertebrate animals.)*

(a) Subcontractor shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2316 and 9 CFR Subpart C, and Section 2.30, and furnish evidence of such registration to ASTRAZENECA before beginning work under this agreement.

(b) Subcontractor shall acquire animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(c) Subcontractor agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 et. seq. and 9 CFR Subchapter A, Parts 1 through 4).

(d) ASTRAZENECA or DARPA may immediately suspend, in whole or in part, work and further payments under this contract for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(1) The suspension will stay in effect until Subcontractor complies with the requirements.
(2) Failure to complete corrective action within the time specified by the Agreements Officer may result in termination of this agreement and removal of Subcontractor's name from the list of Subcontractors with approved Public Health Service Welfare Assurances.

(e) 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), United States Department of Agriculture (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 Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, MD 20782.

(f) Subcontractor shall include this clause, including this paragraph (f), in all subcontracts involving research of live vertebrate animals.

EXPORT CONTROL

(a) *Definition.* "Export-controlled items," as used in this clause, means items subject to the Export Administration Regulations (EAR) (15 CFR Parts 730-774) or the International Traffic in Arms Regulations (ITAR) (22 CFR Parts 120-130). The term includes:

1) "Defense items," defined in the Arms Export Control Act, 22 U.S.C. 2778(j)(4)(A), as defense articles, defense services, and related technical data, and further defined in the ITAR, 22 CFR Part 120.

2) "Items," defined in the EAR as "commodities", "software", and "technology," terms that are also defined in the EAR, 15 CFR 772.1.

(b) Subcontractor shall comply with all applicable laws and regulations regarding export-controlled items. The Department of State will be consulted regarding any questions relating to compliance with the ITAR. The Department of Commerce will be consulted regarding any questions relating to compliance with the EAR.

(c) Subcontractor's responsibility to comply with all applicable laws and regulations regarding export-

controlled items exists independent of, and is not established or limited by, the information provided by this clause.

(d) Nothing in the terms of this Agreement adds, changes, supersedes, or waives any of the requirements of applicable Federal laws, Executive orders, and regulations, including but not limited to—

(1) The Export Administration Act of 1979, as amended (50 U.S.C. App. 2401, *et seq*.);
(2) The Arms Export Control Act (22 U.S.C. 2751, *et seq*.);
(3) The International Emergency Economic Powers Act (50 U.S.C. 1701, et seq.);
(4) The Export Administration Regulations (15 CFR Parts 730-774);
(5) The International Traffic in Arms Regulations (22 CFR Parts 120-130); and
(6) Executive Order 13222, as extended;

(e) Subcontractor shall include the substance of this Article, including this paragraph (e), in all subawards.

CONTINUATION OF ESSENTIAL PERFORMER SERVICES

(a) Definitions. As used in this Article-
(1) Essential Performer service means a service provided by a firm or individual under agreement to DoD to support mission-essential functions, such as support of vital systems, including ships owned, leased, or operated in support of military missions or roles at sea; associated support activities, including installation, garrison, and base support services; and similar services provided to foreign military sales customers under the Security Assistance Program.
> Services are essential if the effectiveness of defense systems or operations has the potential to be seriously impaired by the interruption of these services, as determined by the appropriate functional commander or civilian equivalent.
(2) Mission-essential functions means those organizational activities that must be performed under all circumstances to achieve DoD component missions or responsibilities, as determined by the appropriate functional commander or civilian equivalent. Failure to perform or sustain these functions would significantly affect DoD s ability to provide vital services or exercise authority, direction, and control.
(b) AstraZeneca has identified all or a portion of the Subcontractor services performed under this agreement as essential Performer services in support of mission essential functions.
(c)(1) The Mission-Essential Performer Services Plan submitted by the Subcontractor, is incorporated in this document.
(2) The Performer shall maintain and update its plan as necessary. The Performer shall provide all plan updates to AstraZeneca for approval.
(3) As directed by AstraZeneca, the Performer shall participate in training events, exercises, and drills associated with Government efforts to test the effectiveness of continuity of operations procedures and practices.
(d)(1) Notwithstanding any other clause of this agreement, the Performer shall be responsible to perform those services identified as essential Performer services during crisis situations (as directed by AstraZeneca), in accordance with its Mission-Essential Performer Services Plan.
(2) In the event the Performer anticipates not being able to perform any of the essential Performer services identified in accordance with paragraph (b) of this section during a crisis situation, the Performer shall notify the Agreements Officer or other designated representative as expeditiously as possible and use its best efforts to cooperate with the Government in the Government s efforts to maintain the continuity of operations.
(e) The Government reserves the right in such crisis situations to use Federal employees, military personnel or agreement support from other Performers, or to enter into new agreements for essential Performer services.
(f) Changes. The Performer shall segregate and separately identify all costs incurred in continuing performance of essential services in a crisis situation. The Performer shall notify AstraZeneca of an

increase or decrease in costs within ninety days after continued performance has been directed by AstraZeneca, or within any additional period that AstraZeneca approves in writing, but not later than the date of final payment under the agreement. The Performer's notice shall include the Performer's proposal for an equitable adjustment and any data supporting the increase or decrease in the form prescribed by AstraZeneca. The parties shall negotiate an equitable price adjustment to the agreement price, delivery schedule, or both as soon as is practicable after receipt of the Performer's proposal.
(g) The Performer shall include the substance of this clause, including this paragraph (g), in subawards for the essential services.

SAFEGUARDING DARPA CONTROLLED UNCLASSIFIED INFORMATION AND CONTROLLED TECHNICAL INFORMATION AND CYBER INCIDENT REPORTING
A. Background

Protection of DARPA Controlled Unclassified Information (CUI) and Controlled Technical Information (CTI) is of paramount importance to DARPA and can directly impact the ability of DARPA to successfully conduct its mission. Therefore, this Article requires the performer to protect DARPA CUI and CTI that resides on the performer's information systems. This article also requires the performer to rapidly report any cyber incident involving DARPA CUI or CTI.

B. Safeguarding DARPA CUI and CTI

The performer shall implement NIST Special Publication (SP) 800-171 Rev 1, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations (Dec. 2016), as revised, for DARPA CUI and CTI that resides on the performer's information systems. Consistent with Chapter 2 of NIST SP 800-171 Rev 1, implementation may be tailored to facilitate equivalent safeguarding measures used in the performer systems and organization. Any suspected loss or compromise of DARPA CUI or CTI that resides on the performer's information systems shall be considered a cyber incident and require the performer to rapidly report the incident to DARPA in accordance with paragraph C below.

C. Cyber Incident Reporting

Upon discovery of a cyber incident involving DARPA CUI or CTI, the performer shall take immediate steps to mitigate any further loss or compromise. The performer shall rapidly report the incident to DARPA and provide sufficient details of the event—including identification of detected and isolated malicious software—to enable DARPA to assess the situation and provide feedback to the performer regarding further reporting and potential mitigation actions. The performer shall preserve and protect images of all known affected information systems and all relevant monitoring/packet capture data for at least 90 days from reporting the cyber incident to enable DARPA to assess the cyber incident. The performer agrees to rapidly implement security measures as recommended by DARPA and to provide to DARPA any additionally requested information to help the Parties resolve the cyber incident and to prevent future cyber incidents.

D. <u>Public Release Or Dissemination Of Information</u>
There shall be no dissemination or publication regarding the work performed under this Agreement without prior written approval by AstraZeneca.

E. Lower Tier Agreements

The performer shall include this Article in all subcontracts or lower tier agreements, regardless of tier, for work performed in support of this Agreement.

F. Definitions

Compromise: Disclosure of information to unauthorized persons, or a violation of the security policy of a system, in which unauthorized intentional or unintentional disclosure, modification, destruction, or loss of an object, or the copying of information to unauthorized media may have occurred.
Controlled Technical Information (CTI): Technical information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination. Controlled technical information would meet the criteria, if disseminated, for distribution statements B through F using the criteria set forth in DoD Instruction 5230.24, Distribution Statements on Technical Documents.
Controlled Unclassified Information (CUI): Unclassified information that requires safeguarding or dissemination controls, pursuant to and consistent with applicable law, regulations, and Government-wide policies. The most common type of CUI found in DARPA programs is For Official Use Only (FOUO). The use, marking, dissemination, and storage of CUI can be found in DoD Manual 5200.01 Volume 4 "Controlled Unclassified Information".

Cyber Incident: Actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.
For Official Use Only (FOUO): A protective marking to be applied to controlled unclassified information when disclosure to the public of that particular record, or portion thereof, would reasonably be expected to cause a foreseeable harm to an interest protected by one or more provisions of the FOIA. This includes information that qualifies for protection pursuant to the provisions of the Privacy Act of 1974, as amended. See DoD Manual 5400.07 "DoD Freedom of Information Act (FOIA) Program" for detailed information on categories of information that may qualify for exemption from public release.
Information System: A discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.
Rapidly Report: Report to DARPA within 72 hours of discovery of any cyber incident.

PROTECTION OF HUMAN SUBJECTS

(a) *Definitions*. As used in this clause—
(1) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).
(2) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component s Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.
(3) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.
(4) Institution means any public or private entity or agency (32 CFR 219.102(b)).
(5) Institutional Review Board (IRB) means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).
(6) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).
(b) The Performer shall oversee the execution of the research to ensure compliance with this clause. The Performer shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.
(c) The Performer shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:
(1) The Performer furnishes to the HRPO, with a copy to the Agreements Officer, an assurance of compliance and IRB approval and receives notification from the Agreements Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Performer may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Performer shall notify the Agreements Officer immediately of any suspensions or terminations of the assurance.
(2) The Performer furnishes to the HRPO, with a copy to the Agreements Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Agreements Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Performer s furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the Agreement.
(d) DoD staff, consultants, and advisory groups may independently review and inspect the Performers research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.
(e) Failure of the Performer to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242-15 to immediately suspend, in whole or in part, work and further payment under this Agreement, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Agreements Officer.
(f) The Performer shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

Attachment A: The Mission-Essential Performer Services Plan

Summary of Essential Activities associated with the proposal titled "Development of an end to end pandemic response platform to rapidly discover neutralizing antibodies against pathogens and deliver doses using in vivo expression technologies."
The Tasks/Milestones associated with the project are identified below.

Task 21 Antibody Discovery (Mission Essential)

Task Number	Task Description	Milestone
21.1	Evaluate samples from humanized mice and phage display to find binding antibodies against SARS-CoV-2. Lead identification campaigns will be initiated across 3 platforms: Immune Replica, Phage Display and Hybridoma.	59.1
	Deliverable: List of antibodies identified.	

Task 22 Antibody Evaluation, Developability, and Selection (Mission Essential)

Task Number	Task Description	Milestone
22.12	Evaluate binding of antibodies against Spike protein and a competitive binding to block SARS-2 Receptor binding domain binding to the ACE-2 receptor assay (if applicable) as well as pseudo-neutralization assay. Perform gene synthesis and cloning activities to support developability and future activities.	60.11
	Deliverable: Results of binding and pseudo-neutralization assay.	
22.12	Evaluate non-competing antibodies in wt-neutralization assay	60.12
	Deliverable: Results of neutralization assay.	
22.2	Antibodies that have shown neutralization will be evaluated for developability including sequence liability assessment and stability. Team will evaluate data collected to date to determine two best antibodies to move forward into clinical development and manufacturing.	60.2
	Deliverable: Data review meeting and results of liability and stability assessments	

Task 23 Cell Line Development (Mission Essential)

Task Number	Task Description	Milestone
23.1	Perform activities to generate a stable pool of clones. The resulting cell bank will be tested to confirm absence of endotoxin and mycoplasma.	62.1
	Deliverable: Summary of Testing.	

Task 24 Non-GMP Material (Mission Essential)

Task Number	Task Description	Milestone
24.1	Manufacture research-grade material using a representative process to support in vitro, in vivo and safety (toxicology) studies.	62.1
	Deliverable: Summary of Testing.	

Task 25 Small Scale Manufacturing (Mission Essential)

Task Number	Task Description	Milestone
25.1	Generate GMP Drug Substance material to support IND submission and a Phase 1 clinical study. Two batches (per antibody) will be generated.	63.1
	Deliverable: Certificates of Analyses.	
25.2	Generate GMP Drug Product: Perform fill/finish activities to generate drug product. Pack and label material to support future use.	63.2
	Deliverable: Certificate of Analyses and Example of Label.	

Task 26 In Vivo Testing (Mission Essential)

Task Number	Task Description	Milestone
26.1	Perform animal challenge study in mice to evaluate efficacy of antibody combination.	64.1
	Deliverable: Study report.	
26.2	Perform animal challenge study in non-human primates to evaluate efficacy of antibody combination	
	Deliverable: Study report.	
26.3	Perform safety evaluation in animals to support regulatory submission	
	Deliverable: Study report.	

Task 28 Clinical Study (Mission Essential)

Task Number	Task Description	Milestone
28.1	Author Phase 1 single-ascending dose study protocol	66.1
	Deliverable: Study Protocol.	
28.2	Initiate clinical site(s) to support study including shipment of study material	66.2
	Deliverable: Evidence of First Subject Dose.	
28.3	Complete patient dosing and follow up	66.3
	Deliverable: Memo.	
28.4	Completion of study report	66.4
	Deliverable: Clinical Study Report	