

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

### **(Appendix A)**

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 MedImmune’s TIA with DARPA. As a Subcontractor under the TIA, Subcontractor must meet certain MedImmune’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 MedImmune’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. MedImmune, 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 MedImmune.

### **PUBLIC RELEASE OR DISSEMINATION OF INFORMATION**

At this time, MEDIMMUNE expects the work performed under this Agreement will NOT be fundamental research, and it is, therefore, subject to the following publication restrictions:

There shall be no dissemination or publication regarding the work performed under this Agreement without prior written approval by MEDIMMUNE.

**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 MEDIMMUNE, in accordance with subparagraph B.2 below, that the Subcontractor does not intend to retain title, in which case title shall vest with MedImmune 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, MEDIMMUNE 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 MEDIMMUNE within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to MEDIMMUNE 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 MEDIMMUNE, in writing, within eight (8) months of disclosure to MEDIMMUNE. However, in any case where publication, sale, or public use will be made, Subcontractor shall notify MEDIMMUNE 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 MEDIMMUNE 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 MEDIMMUNE's discretion after considering the circumstances of the Subcontractor and the overall effect of the extension.

6. The Subcontractor shall submit to MEDIMMUNE 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 MEDIMMUNE's written request, the Subcontractor shall convey title to any Subject Invention to MEDIMMUNE 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 MEDIMMUNE and upon actually becoming aware of such failure does not remedy the failure within sixty (60) calendar days; however, MEDIMMUNE 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 MEDIMMUNE, 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 MEDIMMUNE 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 MEDIMMUNE 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 MEDIMMUNE, except when transferred to the successor of that part of the business to which the Subject Invention pertains. MEDIMMUNE approval for license transfer shall not be unreasonably withheld.

2. The Subcontractor's domestic license may be revoked or modified by MEDIMMUNE 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 MEDIMMUNE 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, MEDIMMUNE 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. MEDIMMUNE 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 MEDIMMUNE all instruments necessary to (i) establish or confirm the rights the MEDIMMUNE and/or Government has throughout the world in those Subject Inventions to which the Subcontractor elects to retain title, and (ii) convey title to MEDIMMUNE or DARPA, when requested under paragraph C of this Article and to reasonably cooperate where necessary, at the MEDIMMUNE and/or Government's sole and absolute expense, to enable the MEDIMMUNE and/or Government to file and prosecute patent applications throughout the world to Subject Inventions owned by the MEDIMMUNE 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 MEDIMMUNE in connection with any march-in proceedings undertaken by MEDIMMUNE or Government in accordance with Paragraph I of this Article. MEDIMMUNE 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, MEDIMMUNE 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 MEDIMMUNE.

## **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 MEDIMMUNE 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, MEDIMMUNE 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, MEDIMMUNE or DARPA has the right to grant such a license itself if MEDIMMUNE 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 Acquisition 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 MEDIMMUNE 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 MEDIMMUNE, to deliver at no additional cost to the MEDIMMUNE, all copies of Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. MEDIMMUNE 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 MEDIMMUNE .

#### 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 MEDIMMUNE of any proposed transfers from the Subcontractor of Technology developed under this Agreement to Foreign Firms or Institutions. If MEDIMMUNE or DARPA determines that the transfer may have adverse consequences to the national security interests of the United States, the Subcontractor, its vendors, MEDIMMUNE 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 MEDIMMUNE 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 MEDIMMUNE.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by MEDIMMUNE or DARPA takes place, the Subcontractor shall (a) refund to MEDIMMUNE funds paid for the development of the Technology and (b) the MEDIMMUNE 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 MEDIMMUNE, Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the MEDIMMUNE, 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 MEDIMMUNE 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 MEDIMMUNE 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) MEDIMMUNE 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.