CONTRACT NO. HHSO100200700036C (RETROFIT)
FLOW DOWN REQUIREMENTS FOR
FIRM FIXED-PRICE CONTRACTS

A. INCORPORATION OF FAR CLAUSES

The Federal Acquisition Regulation (FAR) and agency FAR supplement clauses referenced below are incorporated herein by reference, with the same force and effect as if they were stated in full text, and are applicable, including any notes following the clause citation, to this Contract. The Contract Disputes Act, 41 U.S.C. § 601, *et seq.*, shall have no application to this Contract. Any reference to "Disputes" or a "Disputes clause" shall mean the disputes provisions of this Contract.

B. GOVERNMENT SUBCONTRACT

This Contract is entered into by the parties in support of a U.S. Government contract.

As used in the FAR clauses and other clauses incorporated by reference below and otherwise in this Contract:

1. "Commercial Item" means a Commercial Item as defined in FAR § 2.101.

2. "Contract" means this contract.

3. "Contracting Officer" shall mean the U.S. Government Contracting Officer for MEDIMMUNE's government prime contract under which this Contract is entered.

4. "Contractor" and "Offeror" means the SELLER, as defined in this Contract, acting as the immediate (first tier) subcontractor to MEDIMMUNE.

5. "Prime Contract" means the contract between MEDIMMUNE and the U.S. Government or between MEDIMMUNE and its higher-tier contractor who has a contract with the U.S. Government.

6. "Subcontract" means any contract placed by the contractor or lower-tier subcontractors under this Contract.

C. NOTES

1. Substitute “MEDIMMUNE” for “Government” or “United States” throughout this clause.

2. Substitute “MEDIMMUNE Procurement Representative” for “Contracting Officer”, “Administrative Contracting Officer”, and “ACO” throughout this clause.

3. Insert “and MEDIMMUNE” after “Government” throughout this clause.

4. Insert “or MEDIMMUNE” after “Government” throughout this clause.

5. Communication/notification required under this clause from/to the Contractor to/from the Contracting Officer shall be through MEDIMMUNE.

6. Insert “and MEDIMMUNE” after “Contracting Officer”, throughout the clause.

D. AMENDMENTS REQUIRED BY PRIME CONTRACT

Contractor agrees that upon the request of MEDIMMUNE it will negotiate in good faith with MEDIMMUNE relative to amendments to this Contract to incorporate additional provisions herein or to change provisions hereof, as MEDIMMUNE may reasonably deem necessary in order to comply with the provisions of the applicable Prime Contract or with the provisions of amendments to such Prime Contract. If any such amendment to this Contract causes an increase or decrease in the cost of, or the time required for, performance of any part of the Work under this Contract, an equitable adjustment shall be made pursuant to the “Changes” clause of this Contract.

E. PRESERVATION OF THE GOVERNMENT’S RIGHTS

If MEDIMMUNE furnishes designs, drawings, special tooling, equipment, engineering data, or other technical or proprietary information (Furnished Items) which the U. S. Government owns or has the right to authorize the use of, nothing herein shall be construed to mean that MEDIMMUNE, acting on its own behalf, may modify or limit any rights the Government may have to authorize the Contractor’s use of such Furnished Items in support of other U. S. Government prime contracts.

F. CLAUSES INCORPORATED BY REFERENCE

The following clauses from the Federal Acquisition Regulation (FAR) are hereby incorporated in the Contract by reference and shall have the same force and effect as if set forth in full text. The SELLER hereby acknowledges that it has in its possession or is otherwise familiar with all of the referenced clauses incorporated herein by reference and agrees to perform this Contract in accordance with the provisions of such referenced clauses and the other provisions of this Contract. The full text of the referenced clauses may be accessed electronically at various Internet sites, including http://www.arnet.gov.

1. **The following FAR clauses apply to this Contract:**

52.202-1	Definitions	Jul 2004
52.215-16	Facilities Capital Cost of Money	Jun 2003
52.215-17	Waiver of Facilities Cost of Money	Oct 1997
52.215-19	Notification of Ownership Changes (Applicable if this Contract meets the applicability requirements of FAR § 15.408(k). Note 5 applies.)	Oct 1997
52.215-20	Requirements for Cost or Pricing Data or Information Other than Cost or Pricing Data (Note 2 applies.)	Oct 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other than Cost or Pricing Data -- Modifications (Note 2 applies.)	Oct 1997
52.222-21	Prohibition of Segregated Facilities	Feb 1999
52.222-26	Equal Opportunity (Paragraphs (b)(1)-(11) apply.)	Mar 2007
52.222-50	Combating Trafficking in Persons (Note 6 applies)	Apr 2006
52.225-1	Buy American Act – Supplies (Applicable if the work contains other than domestic components. Note 2 applies to the first time "Contracting Officer" is mentioned in paragraph (c).)	Jun 2003
52.225-13	Restrictions on Certain Foreign Purchases	Feb 2006
52.227-1	Authorization and Consent, Alternate I (Apr 1984)	Jul 1995

52.227-11	Patent Rights – Retention by the Contractor (Short Form) (Applicable if this Contract includes, at any tier, experimental, developmental, or research work and the Contractor is a small business concern or domestic nonprofit organization. Paragraph (f) is modified to include requirements in FAR § 27.303(a)(2)(i) through (iv). The frequency of reporting is annual. Reports required by this clause shall be filed with the agency identified in this Contract. If no agency is identified, contact the MEDIMMUNE Procurement Representative identified on the face of this Contract. FAR § 52.227-12, Patent Rights -- Retention by the Contractor (Long Form) shall be included in all other subcontracts, regardless of tier, for experimental, developmental, or research work.)	Jun 1997
52.227-14	Rights in Data - General Alternate II (Jun 1987) (To the Limited Rights Notice, add subparagraph (g)(2)(a)(i), "Use (except for manufacture) by support service contractors.")	Jun 1987
52.233-3	Protest After Award (Aug 1996) Alternate I (Jun 1985) (In the event MEDIMMUNE's customer has directed MEDIMMUNE to stop performance of the Work under the Prime Contract under which this Contract is issued pursuant to FAR Subpart 33.1, MEDIMMUNE may, by written order to Contractor, direct Contractor to stop performance of the Work called for by this Contract. "30 days" means "20 days" in paragraph (b)(2). Note 1 applies, except the first time "Government" appears in paragraph (f). In paragraph (f) add after "33.104(h)(1)" the following: "and recovers those costs from MEDIMMUNE.")	
52.242-15	Stop-Work Order (Apr 1984) (Notes 1 and 2 apply.)	Aug 1989
52.243-1	Changes – Fixed-Price (Notes 1 and 2 apply.)	Aug 1987
52.244-2	Subcontracts, Alternate I (Jan 2006) (Note 2 applies.)	Aug 1998
52.244-6	Subcontracts for Commercial Items	Mar 2007
52.245-2	Government Property (Fixed-Price Contracts) (Except for paragraphs (i) and (j), Note 1 applies except in the phrases "Government property," "Government-furnished property," and in reference to title to property. Note 2 applies.	May 2004

	Paragraphs (c)(1), (c)(2), (c)(3) and (c)(4) are deleted and replaced with the following: "The Government shall retain title to all Government-furnished property. Title to all property purchased by the Contractor for which the Contractor is entitled to be reimbursed as a direct item of cost under this Contract shall pass to and vest in MEDIMMUNE upon the vendor's delivery of such property. Contractor shall furnish to the MEDIMMUNE Procurement Representative a list of all equipment to which title is vested in MEDIMMUNE under this paragraph within 5 days following the end of the quarter during which it was received or purchased. Title to Government or MEDIMMUNE property shall not be affected by its incorporation into or attachment to any property not owned by the Government or MEDIMMUNE, nor shall Government or MEDIMMUNE property become a fixture or lose its identity as personal property by being attached to any real property." The following is added as paragraph (m): "Seller shall provide to MEDIMMUNE immediate notice of any disapproval, withdrawal of approval, or nonacceptance by the Government of property control system." Disposition of property under paragraphs (i) and (j) shall be coordinated with MEDIMMUNE.	
52.246-9	Inspection of Research and Development – Short Form (Note 1 applies.)	Apr 1984
52.249-2	Termination for Convenience of the Government (Fixed-Price) (Notes 1 and 2 apply. Note 4 applies to the first time "Government" appears in paragraphs (b)(4) and (b)(6), it applies to all of paragraph (b)(8) and it applies to the second time "Government" appears in paragraph (d). In paragraph (n) "Government" means "MEDIMMUNE and the Government." In paragraph (c), "120 days" is changed to "60 days." In paragraph (d) "15 days" is changed to "30 days," and "45 days" is changed to "60 days." In paragraph (e), "1 year is changed to 6 months." Paragraph (j) is deleted. In paragraph (l), "90 days is changed to "45 days." Settlements and payments under this clause may be subject to the approval of the Contracting Officer.)	May 2004
52.249-8	Default (Fixed-Price Supply and Service) (Notes 1 and 2 apply, except Note 1 is not applicable to paragraph (c).	Apr 1984

Note 4 applies to the second and third times "Government" appears in paragraph (e). Timely performance is a material element of this Contract.)

2. **The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $10,000:**

52.222-36	Affirmative Action for Workers with Disabilities	Jun 1998

3. **The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $30,000:**

52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Note 2 applies.)	Jan 2005

4. **The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $100,000:**

52.203-6	Restrictions on Subcontractor Sales to Government	Sep 2006
52.203-7	Anti-Kickback Procedures	Jul 1995
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Jun 2003
52.215-2	Audit and Records – Negotiation (Note 6 applies.)	Jun 1999
52.215-14	Integrity of Unit Prices (Delete paragraph (b) of the clause.)	Oct 1997
52.219-8	Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns	May 2004
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	Sep 2006
52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and other Eligible Veterans	Sep 2006
52.223-14	Toxic Chemical Release Reports (Note 2 applies. Delete paragraph (e).)	Aug 2003
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Notes 2 and 4 apply.)	Aug 1996

52.232-17	Interest (Note 1 applies.)	Jun 1996
52.242-13	Bankruptcy (Notes 1 and 2 apply.)	Jul 1995
52.244-5	Competition in Subcontracting	Dec 1996

5. **The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $500,000:**

52.219-9	Small Business Subcontracting Plan (Applicable if the Contractor is not a small business. Note 2 is applicable to subparagraph (c) only. The contractor's subcontracting plan is incorporated herein by reference.)	Sep 2006
52.230-2	Cost Accounting Standards (Applicable if SELLER is subject to cost accounting standards. "United States" means "United States or MEDIMMUNE." Subparagraph (b) is deleted.)	Apr 1998
52.230-3	Disclosure and Consistency of Cost Accounting Practices (Applicable if SELLER is subject to modified CAS coverage.)	Apr 1998
52.230-6	Administration of Cost Accounting Standards (Applicable if FAR § 52.230-2 or FAR § 52.230-3 applies.)	Apr 2005

6. **The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $550,000:**

52.215-10	Price Reduction for Defective Cost or Pricing Data (Notes 2 and 4 apply except the first time "Contracting Officer" appears in paragraph (c)(1). Rights and obligations under this clause shall survive completion of the Work and final payment under this Contract.)	Oct 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data – Modifications (Notes 2 and 4 apply except the first time "Contracting Officer" appears in paragraph (d)(1). Rights and obligations under this clause shall survive completion of the Work and final payment under this Contract.)	Oct 1997
52.215-12	Subcontractor Cost or Pricing Data	Oct 1997
52.215-13	Subcontractor Cost or Pricing Data – Modifications	Oct 1997

52.215-15	Pension Adjustments and Asset Reversions (Applicable if this Contract meets the applicability requirements of FAR § 15.408(g). Note 5 applies.)	Oct 2004
52.215-18	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions (Applicable if this Contract meets the applicability requirements of FAR § 15.408(j). Note 5 applies.)	Jul 2005

G. HHSAR CLAUSES

352.202-1	Definitions – With Alternate Paragraph (h) (Jun 2001)	Jan 2006
352.223-70	Safety and health (Note 5 applies.)	Jan 2006
352.224-70	Confidentiality of Information (Note 2 applies to paragraph (c). Note 5 applies to paragraph (f) and (g).)	Jan 2006
352.270-5	Key Personnel	Jan 2006
352.270-6	Publications and Publicity ("Project officer" means MEDIMMUNE Procurement Representative. Note 3 applies.)	Jan 2006
352.270-7	Paperwork Reduction Act (Applies to any contract requiring collection of information from 10 or more persons that are not federal employees. Note 5 applies, and all communications to and from the Project Officer shall be through MEDIMMUNE.)	Jan 2006
352.270-8	Protection of Human Subjects (Applicable to solicitations and resultant contracts involving human subjects. Note 2 applies to subparagraph (c). Consultation contemplated by subparagraph (c) shall not be required of MEDIMMUNE.) Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human Subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.	Jan 2006
352.270-9	Care of Live Vertebrate Animals (Applicable to solicitations and resultant contracts involving research on vertebrate animals. Note 2 applies. Consultation contemplated by	Jan 2006

subparagraph (d) shall not be required of MEDIMMUNE.)

H. ADDITIONAL CONTRACT CLAUSES

1. 52.222-39 Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004)

   (a) Definition. As used in this clause –

      (1) "United States" means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

   (b) Except as provided in paragraph (e) of this clause, during the term of this Contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

      Notice to Employees

      Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

      If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contact administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in port to

support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR Part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this Contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR Part 470, Subpart B – Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR Part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to –

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that –

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall –

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this Contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR Part 470, Subpart B – Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interest of the United States.

I. SPECIAL CONTRACT REQUIREMENTS

1. Human Subjects

Research involving human subjects shall not be conducted under this Contract until the protocol has been approved by DHHS, written notice of such approval has been provided by the Contracting Officer or the MEDIMMUNE PROCUREMENT REPRESENTATIVE, and the Contractor has provided to the Contracting Officer through MEDIMMUNE a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

2. Human Materials

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this Contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

3. **Animal Welfare Assurance**

The Contractor shall obtain, prior to the start of any work under this Contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this Contract, and any subcontractors performing work under this Contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

4. **Confidentiality of Information**

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APR 1984): Information or data of a personal nature about any individual participant in any clinical study under this Contract.

5. **Review and Approval**

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this Contract without written notice in advance to the Government through MEDIMMUNE.

6. **Identification and Disposition of Data**

The Contractor through MEDIMMUNE will be required to provide certain data generated under this Contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this Contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this Contract for the time specified by the FDA.

7. **EPA Energy Star Requirements**

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-

power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

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

8. **Needle Exchange**

Pursuant to Section 505 of Public Law 105-78, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

9. **Prohibition on Contractor Involvement with Terrorist Activities**

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

10. **Manufacturing Standards**

The Current Good Manufacturing Practice requirement (CGMP) of the Federal Food, Drug and Cosmetic Act (FDCA section 501(a)(2)(B); the CGMP regulations for finished pharmaceuticals (21 CFR Parts 210-211); and applicable regulations governing biological products (21 CFR Parts 600-610) will be the standards to be applied for manufacturing, processing and packing of this vaccine product.

If at any time during the life of the contract, the SELLER fails to comply with CGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER or MEDIMMUNE, the Offeror shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Offeror fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

11. **Anti-Lobbying Provisions**

The Contractor is hereby notified of the restrictions on the U.S. Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, subcontract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, and officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the mailing of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or and State or Local legislature.

12. **Possession, Use and Transfer of Selected Biological Agents or Toxins**

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins: Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety); Agricultural Bioterrorism Protection Act of 2002, which consists of 7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins (relating to plant health or plant products); and 9 CFR Part 121, Possession, Use and Transfer of Biological Agents and Toxins (relating to human and animal health, animal health or animal products) – December 13, 2002.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this Contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using DHHS funds for research involving Select Agents. No DHHS funds can be used for research involving Select Agents if the final registration certificate is denied. For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this Contract, the institution must provide information satisfactory to the DHHS that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. In the technical proposal, the offeror must include details about the select agent and the quantity proposed to be used during contract performance. When requested by the Government or MEDIMMUNE PROCUREMENT REPRESENTATIVE during negotiations, potential awardees must provide information addressing the following key elements for the foreign institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. A NIAID-chaired committee of U.S. federal employees (including representatives of DHHS grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. Toward this end, when requested during negotiations, potential awardees will be asked to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training

plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, foreign institutions must provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the resulting contract. If the proposed contract work will not involve Select Agents, the offeror must include a statement in their technical proposal that the proposed work does not now nor will it in the future (*i.e.,* throughout the life of the award) involve Select Agents. Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program.

The contractor shall not conduct work involving select agents or toxins under this Contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this Contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag selectagent/FinalRule3-18-05.pdf), as required, before using DHHS funds for research involving Select Agents. No DHHS funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer Select Agents under this Contract, before using DHHS funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the DHHS that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

(http://www.aphis.usda.gov/programs/ag selectagent/FinalRule3-18-05.pdf)

are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an HHS representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An DHHS-chaired committee of U.S. federal employees (including representatives of select DHHS grants/contracts and scientific program

management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the OPHEMC Director, DHHS. The Director (or designee) will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No DHHS funds can be used for research involving Select Agents at a foreign institution until DHHS grants this approval.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http:/www.cdc.gov/od/sap/ and http:www.cdc.gov/od/sap/docs/salist.pdf. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at:

http://www.aphis.usda.gov/programs/ag_selectagent/index.html; and

http://www.aphis.usda.gov/programs/ag selectagent/ag_bioterr_forms.html

For foreign institutions, see the NIAID Select Agent Award information:

http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm.