CONTRACT NO. HHSO100200900002I (H1N1)
FLOWDOWN REQUIREMENTS FOR
COMMERCIAL ITEM CONTRACTS

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.

I. INCORPORATION OF FAR CLAUSES

The Federal Acquisition Regulation (FAR) 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. If the date or substance of any of the clauses listed below is different from the date or substance of the clause actually incorporated in the Prime Contract referenced by number herein, the date or substance of the clause incorporated by said Prime Contract shall apply instead. 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.

A. 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.

B. 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.

C. 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 Vendor hereby acknowledges that is 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://farsite.hill.af.mil/ and http://www.arnet.gov.

	REFERENCE	TITLE
1.	The following FAR clauses apply to this Contract:	
(a)	52.215-21	REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA - MODIFICATIONS (OCT 1997) (Note 2 applies.)
(b)	52.222-21	PROHIBITION OF SEGREGATED FACILITIES (FEB 1999)
(c)	52.222-26	EQUAL OPPORTUNITY (MAR 2007) (Paragraphs (b)(1)-(11) apply.) **[NOT APPLICABLE OUTSIDE U.S.]**
(d)	52.222-41	SERVICE CONTRACT ACT OF 1965 (NOV 2007)
(e)	52.222-50	COMBATING TRAFFICKING IN PERSONS (FEB 2009)
(f)	52.225-13	RESTRICTIONS ON CERTAIN FOREIGN PURCHASES (JUNE 2008)
(g)	52.243-1	CHANGES - FIXED PRICE (AUG 1987) (Applicable to supplies.)
(h)	52.243-1 ALTERNATE I	CHANGES - FIXED PRICE (AUG 1987) (Applicable to services.)
(i)	52.243-1 ALTERNATE II	CHANGES - FIXED PRICE (AUG 1987) (Applicable to supplies and services)
(j)	52.244-6	SUBCONTRACTS FOR COMMERCIAL ITEMS (MAR 2009)
(k)	52.247-64	PREFERENCE FOR PRIVATELY OWNED U.S. FLAG COMMERCIAL VESSELS (FEB 2006) (Applicable if the contract may involve ocean transportation of supplies subject to the Cargo Preference Act of 1954.)
(l)	52.249-2	TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT (FIXED-PRICE) (MAY 2004)
2.	The following FAR clauses apply to this Contract if the value of this Contract equals or exceeds $10,000:	
(a)	52.222-36	AFFIRMATIVE ACTION FOR WORKERS WITH DISABILITIES (JUNE 1998) **[NOT APPLICABLE WHEN BOTH THE PERFORMANCE OF THE WORK AND THE RECRUITMENT OF WORKERS WILL OCCUR OUTSIDE OF THE U.S.]**

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

(a) 52.219-8 UTILIZATION OF SMALL BUSINESS CONCERNS (MAY 2004) **[NOT APPLICABLE OUTSIDE U.S.]**

(b) 52.222-35 EQUAL OPPORTUNITY FOR SPECIAL DISABLED VETERANS, VETERANS OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS (SEPT 2006) **[NOT APPLICABLE OUTSIDE U.S.]**

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

(a) 52.203-13 CONTRACTOR CODE OF BUSINESS ETHICS AND CONDUCT (DEC 2008) (In section (b) substitute "MEDIMMUNE" for "Contracting Officer" the first time "Contracting Officer" is used.) (Applicable if the performance period is 120 days or more; in section.)

5. The following FAR clauses apply to this Contract as indicated:

(a) 52.225-1 BUY AMERICAN ACT-SUPPLIES (FEB 2009) (Applicable if the Work contains other than domestic components. Note 2 applies to the first time "Contracting Officer" is mentioned in paragraph (c).)

D. <u>ADDITIONAL CLAUSES</u>

1. 52.222-39 Notification of Employee Rights Concerning Payment of Union Dues or Fees **[NOT APPLICABLE OUTSIDE U.S.]**

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.

II. ADDITIONAL TERMS & CONDITIONS

1. Site Visits, Audits, & Collection of Samples. At the discretion of MedImmune and independent of testing conducted by the Contractor, MedImmune reserves the right to conduct site visits and audits on an as-needed basis, and collect samples of product and key intermediates held by the Contractor with three (3) calendar days notice to Contractor. However, in the event of an emergency MedImmune reserves the right to suspend the 3 day notice to Contractor. Site visits and audits may address areas to include, but not limited to, security, regulatory and quality, manufacturing plant and production, testing and development laboratories, and GMP/GLP/GCP compliance. MedImmune may conduct a cGMP, GLP, or GCP audit of all Contractor facilities/sites (including sub-contractor facilities) under this contract annually and as cause dictates. The Contractor shall provide a written response including appropriate corrective actions within 30 calendar days after receipt of an audit report prepared in response to an audit or site visit conducted under this clause.

2. Access and Disposition of Documentation and Data. MedImmune shall have physical access upon demand to all documentation and data generated under this contract, including, but not limited to: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, and all Contractor commitments and responses.

3. Study Design Review Meetings. For each non-clinical and clinical study, the Contractor shall distribute draft study plans and protocols for MedImmune review prior to the conduct of a Study Design Review Meeting between MedImmune and the USG as part of the pre-approval process. The Contractor performing the study shall participate in pre-design meetings with MedImmune and the USG for all non-clinical and clinical studies. Review meetings will be held at the request of MedImmune, to enhance communications between the MedImmune and the Contractor.

4. Meetings and Conferences. In addition to any other requirements set forth in this contract, Contractor may be required to participate in regular meetings to coordinate and oversee the contract effort as directed by MedImmune. Such meetings may include, but are not limited to, meetings of other H1N1 prime contractors and subcontractors, MedImmune, other MedImmune subcontractors, and the USG to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, clinical study designs and regulatory issues, meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor Weekly and monthly teleconferences with the Contractor, MedImmune, and the USGas directed by MedImmune, with HHS officials will be held at times and dates to be determined by MedImmune to review technical and product development progress, except during clinical lot manufacturing when meetings shall be held on a weekly basis. In addition, MedImmune may schedule progress reviews, including quarterly progress reviews, on-site at the Contractor's facilities and other locations.

5. Confidentiality of Information. Disclosure of the information, data, paperwork, records, electronic media, material (including biological) or similar items ("Confidential Data/Materials") which the Contractor develops or will have access to as a result of this contract is prohibited. It is understood that throughout performance of this contract, the Contractor will have access to Confidential Data/Materials, which is the sole property of MedImmune, the Federal Government, U.S. Department of Health and Human Services (DHHS) or is otherwise entrusted to MedImmune. The Contractor and its subcontractor(s) (if any) agree to maintain the confidentiality of all Confidential Data/Materials to which access may be gained throughout contract performance, wherever title thereto vests. The Contractor and his subcontractor(s) (if any) agree to not

disclose said Confidential Data/Materials, any interpretations and/or translations thereof, or information/data/material derivative there-from, to unauthorized parties in contravention of these provisions, without the prior written approval of MedImmune. Subcontractors are subject to the same stipulations and may be held responsible for any violations of confidentiality. All Confidential Data/Material, which is the sole property of MedImmune or the Federal Government, U.S. Department of Health and Human Services (DHHS) or is otherwise entrusted to MedImmune, will remain property of that party, and must be relinquished to that party at the termination of work; provided, however, Contractor may retain one copy in its legal files for verification, compliance and dispute resolution purposes.

6. Confidentiality of Information.

(a) MedImmune, in coordination with the USG, has determined that this contract involves access to, and creation, distribution, and use of, sensitive information, confidential information, and other non-public information ("Protected Data/Materials"). Non-public information is information, data, paperwork, records, electronic media, material or similar items that is known, or reasonably should be known, not to have been made available to the general public. Contractor shall mark all Protected Data/Materials created by Contractor. Examples of Protected Data/Materials include, but are not limited to information/data/materials/et cetera that is:

(1) routinely exempt from disclosure under 5 U.S.C. 552 or otherwise protected from disclosure by statute, Executive order or regulation;

(2) designated as non-public by any government agency;

(3) has not actually been disseminated to the general public and is not authorized to be made available to the public on request; or

(4) not independently developed by Contractor without benefit of Protected Data/Materials.

(b) Contractor shall guarantee strict confidentiality of Protected Data/Materials, and shall not release, publicize, or make known such Protected Data/Materials in any manner. Further, the Contractor agrees to use such Protected Data/Materials only under the following conditions:

(1) Contractor shall

(i) use the Protected Data/Materials only for the purposes of carrying out the work required by the contract;

(ii) not disclose the Protected Data/Materials to anyone other than the contracting officer, his duly appointed project officer(s), or as otherwise authorized under this contract; and

(iii) return the information/data/material whenever the information/data/material is no longer required by the Contractor for performance or upon completion of the contract, whichever is sooner; provided, however, Contractor may retain one copy in its legal files for verification, compliance and dispute resolution purposes.

(2) Contractor shall obtain a written confidentiality/non-disclosure agreements to honor the limitations of this clause from each of the Contractor's employees who will have access to Protected Data/Materials before the employee is allowed access.

(3) Contractor agrees that these contract conditions concerning the use and disclosure of such Protected Data/Materials are included for the benefit of, and shall be enforceable by, the Government and any affected person, business, or organization having a proprietary interest in the information/data/material.

(4) The Contractor shall not use any Protected Data/Materials to compete with any person, business, or organization having a proprietary interest in the Protected Data/Materials.

(5) The Contractor agrees to obtain the written consent of MedImmune prior to entering into any subcontract that will involve the disclosure of Protected Data/Materials by the Contractor to the subcontractor.

(6) If Contractor, through an employee or otherwise, is subpoenaed to testify or produce documents, or to disseminate any Protected Data/Materials to comply with any law, rule, regulation, court ruling or similar order, which could result in disclosure of such Protected Data/Materials, then the Contractor must provide immediate advance notification to MedImmune so that the Government may authorize such disclosure, or have the opportunity to take action to prevent such disclosure.

(c) Contractor shall submit any request for waiver of this provision to MedImmune. Disclosure of any Protected Data/Materials, in whole or in part, by the Contractor shall only be made after receipt of signed, written approval from the MedImmune in coordination with the USG. Whenever the Contractor is uncertain with regard to the proper handling of Protected Data/Materials under the contract, the Contractor shall obtain a written determination from MedImmune.

(d) The Contractor agrees that this provision is a material part of this contract and that any disclosure of such Protected Data/Materials is in violation of this contract and maybe a violation of applicable law. Remedies for noncompliance herewith include default, or other contractual actions, as well as civil or criminal remedies authorized by law.

(e) The requirements of this clause shall survive the termination or expiration of this contract and shall continue in perpetuity.

(f) The Contractor agrees to include a clause substantially the same as this clause in each subcontract at any tier.

7. Inspections. MedImmune reserves the right to conduct announced or unannounced inspections of manufacturing and storage facilities of the contractor or subcontractor at any tier, and to conduct an audit, either performed by MedImmune, the USG or its contractor(s), of the facilities used under this contract and of all records related to the manufacture, testing and storage of the product.

8. Interactions with Regulatory Agencies. The obligations set forth in this paragraph shall apply to the contractor and any subcontract at any tier thereunder.

(a) The Contractor shall prepare and submit to MedImmune initial draft minutes and final accepted minutes of all formal meetings between Contract and U.S. regulatory agencies, to include FDA.

(b) The Contractor shall prepare and submit to MedImmune initial draft minutes and the final accepted minutes of all informal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(c) The Contractor shall forward to MedImmune the dates and times of all scheduled meetings with U.S. regulatory agencies, to include FDA, to BARDA and make arrangements for appropriate BARDA staff to attend such U.S. regulatory agencies meetings.

(d) The Contractor shall provide MedImmune the opportunity to review and comment upon any documents to be submitted to U.S. regulatory agencies. The Contractor shall provide MedImmune with 3 business days, or such shorter period as may be practicable in time-sensitive situations, to review and provide comments to the Contractor prior to its submittal to U.S. regulatory agencies.

(e) The Contractor shall furnish all findings of U.S. regulatory agencies inspections, including FDA form 482 and 483 inspection notice and observations and Establishment Inspection Reports (EIR) pertinent to the contract, to MedImmune within 48 hours of receipt.

(f) The Contractor shall notify MedImmune of all site visits/audits by U.S. regulatory agencies, to include FDA, within 24 hours of agency personnel's arrival.

(g) The Contractor shall include MedImmune in all scheduled meetings and teleconferences with U.S. regulatory agencies.

9. Anti-Lobbying Provisions. The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 31, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, 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, an 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 making 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 the 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 the 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, the State, or the Local legislature.

10. Possession, Use and Transfer of Selected Biological Agents or Toxins. Contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

(a) For this contract 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 C.F.R. part 73, 7 C.F.R. part 331, and/or 9 C.F.R. part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using BARDA funds for research or production and testing involving Select Agents. No BARDA funds can be used for research involving Select Agents if the final registration certificate is denied.

(b) For this contract or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, before using BARDA funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to MedImmune/BARDA, that safety, security, and training standards equivalent to those described in 42 C.F.R. part 73, 7 C.F.R. part 331, and/or 9 C.F.R. 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 a BARDA 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 BARDA chaired committee of U.S. federal employees (including representatives of BARDA 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 C.F.R. part 73, 7 C.F.R. part 331, and/or 9 C.F.R. part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the BARDA Director. The BARDA Director will make the approval decision and notify MedImmune/Contractor. MedImmune will inform Contractor of the approval status of the foreign institution. No BARDA funds can be used for research involving Select Agents at a foreign institution until BARDA grants this approval.

(c) 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 Website 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.

(d) For foreign institutions, see the NIAID Select Agent Award information: http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm.

11. Human Subjects. Research involving human subjects shall not be conducted under this contract until the study protocols have been approved by MedImmune/BARDA, written notice of such approval has been provided to Contractor and the Contractor has provided to MedImmune a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly 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 "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

12. Protection of Human Subjects. No performance of work involving human subjects research shall be performed until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee(s) as described in 45 C.F.R. Part 46. Contracts involving human subjects will not be awarded to an individual unless the individual is affiliated with or sponsored by an institution that has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. The Contractor further agrees to provide certification at least annually that the institutional review board (IRB) has reviewed and approved the procedures which involve human subjects in accordance with 45 C.F.R. Part 46 and the Assurance of Compliance.

The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. To the extent not inconsistent with the terms of this contract, the parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of MedImmune. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of MedImmune for the acts of the Contractor or its employees.

If at any time during performance of this contract, MedImmune determines, in consultation with the government and OHRP, that the Contractor is not in compliance with any of the requirements and standards stated herein, MedImmune may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

If the Contractor fails to complete corrective action within the period of time designated in MedImmune's written notice of suspension, MedImmune may terminate this contract in whole or in part.

13. Laboratory License Requirements. The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act, as amended). This requirement shall also be included in any subcontract for services under the contract.

14. Manufacturing Standards. The Current Good Manufacturing Practice Regulations ("cGMP") (21 C.F.R. Parts 210-211) and regulations pertaining to biological products (21 C.F.R. Part 600) will be the standard to be applied for manufacturing, processing, packing, storage, and delivery of this product.

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

15. Care of Live Vertebrate Animals.

(a) Before undertaking performance of any contract involving research on live vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 C.F.R. Section 2.30. The Contractor shall furnish evidence of such registration to MedImmune without demand.

(b) The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 C.F.R. Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 C.F.R. Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, MedImmune determines, in consultation with the Contracting Officer and the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards herein stated, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in MedImmune's written notice of suspension, MedImmune may terminate this contract in whole or in part.

(e) The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector 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: Animal Care Staff USDA/APHIS 4700 River Road, Unit 84 Riverdale, MD 20737 (301) 734-4980. Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

16. Information on Compliance with Animal Care Requirements.

(a) Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. The USDA office contact information is available at http://www.aphis.usda.gov/ac/acorg.html. They are responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

(b) The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

(c) The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 C.F.R., Subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

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

17. Approval of Required Assurance by OLAW.Under governing regulations, federal funds which are administered by BARDA shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. Section 2316 and 9 C.F.R. Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW) with a copy of such assurance submitted to MedImmune without demand. Each performance site (if any) must also assure compliance with 7 U.S.C. Section 2316 and 9 C.F.R. Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. Section 2316 and 9 C.F.R.

Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/olawaddr.htm.

18. Release of Contractor Confidential Information.

Contractor acknowledges that information provided by Contractor to MedImmune pursuant to this contract may in turn be subject to the following:

(a) The Department of Health and Human Services ("HHS") may find it necessary to release information submitted by MedImmune to HHS pursuant to the provisions of the prime contract, to individuals not employed by HHS. Information that is ordinarily entitled to confidential treatment under applicable law may be included in the information released to these individuals. Accordingly, by submission of this quotation or signature on this contract or other contracts, the Contractor hereby consents to a limited release of its confidential information ("CI") provided that such information is not released to other companies that manufacture an influenza vaccine.

(b) Possible circumstances where HHS may release the Contractor's CI include, but are not limited to, the following:

(1) To HHS support service contractors tasked with assisting HHS in the administration, evaluation, audit, or handling and processing information and documents in the award, administration, or termination of HHS contracts.

(2) To entities such as the Government Accountability Office, boards of contract appeals, and courts of competent jurisdiction in the resolution of solicitation or contract protests and disputes.

(3) To HHS contractor employees engaged in information systems analysis, development, operation, and maintenance, including performing data processing and management functions for HHS.

(4) Pursuant to a court order or court-supervised agreement.

(c) HHS recognizes an obligation to protect the Contractor from competitive harm that may result from the release of CI to a competitor. Except where otherwise provided by law, HHS will only permit the release of CI pursuant to a confidentiality/non-disclosure agreement.

(d) This clause does not authorize HHS to release the Contractor's CI to the public pursuant to a request filed under the Freedom of Information Act.

(e) The Contractor agrees to include this clause, including this paragraph (e), in all subcontracts at any tier awarded pursuant to this contract that require the furnishing of confidential business information by the subcontractor.

19. Cooperation with Government Contractors.

(a) As directed by MedImmune, the Contractor shall cooperate under this Contract in a complementary, responsive and timely manner with other persons or entities that may be retained by MedImmune or the Government; provided that Contractor will not be required to cooperate or share information pursuant to this paragraph with other contractors that manufacture an influenza vaccine.

(b) Other entities are not authorized to direct Contractor in any manner.

(c) Contracts with other entities will contain a confidentiality/non-disclosure clause that requires said contractors to protect shared information and prohibits such contractors from using the information for any purpose other than that for which the information was furnished.

(d) Neither the Contractor nor its subcontractors shall be required in the satisfaction of the requirements of this paragraph to perform any effort or supply any documentation not otherwise required by this contract or subcontract.

(e) The Contractor agrees to include this clause in each subcontract at any tier. This agreement neither relieves the Contractor of responsibility to manage subcontracts effectively and efficiently, nor is it intended to establish privity of contracts between the USG or other entities and such subcontractors.

20. Prohibition of 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.

21. Disputes. All disputes under this Contract which are not disposed of by mutual agreement shall be decided by recourse to an action at law or equity. Until final resolution of any dispute hereunder, Contractor shall diligently proceed with the performance of this Contract as directed by MedImmune. All claims for monies due or to become due from Contractor shall be subject to deduction by MedImmune for recoupment, set off or counterclaim arising out of this or any other of MedImmune's agreements with Contractor.

22. Governing Law. Notwithstanding any choice of law provision within the Contract to the contrary, any provision in this Contract that is (a) incorporated in full text or by reference from the FAR, or (b) incorporated in full text or by reference from any agency regulation that implements or supplements the FAR or (c) that is substantially based on any such agency regulation or FAR provision, shall be construed and interpreted according to the federal common law of Government contracts as enunciated and applied by federal judicial bodies, boards of contracts appeals, and quasi-judicial agencies of the federal Government.

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