

AN ORDINANCE 2014 - 08 - 07 - 0 544

AUTHORIZING AN INFLUENZA REAGENT RESOURCE AGREEMENT WITH THE AMERICAN TYPE CULTURE COLLECTION TO PROVIDE THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT'S BIOTERRORISM AND INFLUENZA SURVEILLANCE LAB WITH FREE REAGENTS FOR THE BENEFIT OF THE PUBLIC HEALTH COMMUNITY FROM THE CENTERS FOR DISEASE CONTROL & PREVENTION.

* * * * *

WHEREAS, the Centers for Disease Control and Prevention (CDC) works year round to improve and enhance international influenza surveillance efforts and to build global laboratory capacity in preparation for a future pandemic; and

WHEREAS, in September 2008, CDC's Influenza Division contracted with the American Type Culture Collection (ATCC), a not-for-profit organization, to implement the Influenza Reagent Resource (IRR); and

WHEREAS, the IRR, funded by the CDC, is a biological reagent repository established to provide free access to influenza virus strains and research reagents; and

WHEREAS, the IRR resources are available to public health facilities, research institutions, life science companies and other entities, agencies and institutions; and

WHEREAS, reagents will be manufactured and distributed by the IRR to increase the availability and accessibility of influenza viruses and reagents for public health purposes; and

WHEREAS, this agreement will govern the transfer of research materials between the San Antonio Metropolitan Health District and the ATCC and the use of the research materials; **NOW THEREFORE:**

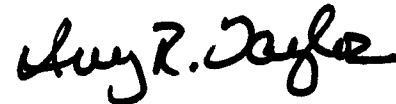
BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The City Manager or her designee or the Director of the San Antonio Metropolitan Health District (Metro Health) or his designee is authorized to execute an Influenza Reagent Resource Agreement with the American Type Culture Collection to provide Metro Health's Bioterrorism and Influenza Surveillance Lab with free reagents for the benefit of the public health community from the Centers for Disease Control & Prevention. A copy of the agreement in substantially final form is attached hereto and incorporated herein for all purposes as **Attachment I.**

SECTION 2. The financial allocations in this Ordinance are subject to approval by the Director of Finance, City of San Antonio. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocations to specific SAP Fund Numbers, SAP Project Definitions, SAP WBS Elements, SAP Internal Orders, SAP Fund Centers, SAP Cost Centers, SAP Functional Areas, SAP Funds Reservation Document Numbers, and SAP GL Accounts as necessary to carry out the purpose of this Ordinance.

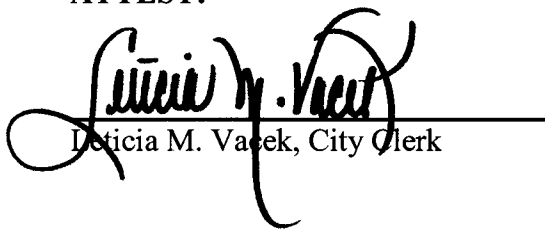
SECTION 3. This ordinance is effective immediately upon the receipt of eight affirmative votes; otherwise, it is effective ten days after passage.

PASSED AND APPROVED this 7th day of August, 2014.

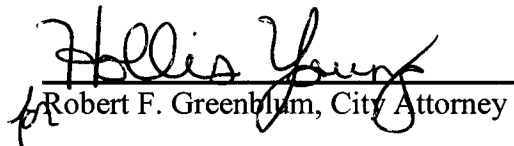


M A Y O R
Ivy R. Taylor

ATTEST:


Leticia M. Vacek, City Clerk

APPROVED AS TO FORM:


Robert F. Greenblum, City Attorney

Agenda Item:	27 (in consent vote: 6, 7, 8, 9, 12, 13, 15, 16, 17A, 17B, 17C, 17D, 18, 19, 21, 22, 23, 24, 25, 26, 27)
Date:	08/07/2014
Time:	11:34:24 AM
Vote Type:	Motion to Approve
Description:	An Ordinance authorizing an Influenza Reagent Resource Agreement with the American Type Culture Collection to provide the San Antonio Metropolitan Health District's Bioterrorism and Influenza Surveillance Lab with free reagents for the benefit of the public health community from the Centers for Disease Control & Prevention. [Gloria Hurtado, Assistant City Manager; Dr. Thomas L. Schlenker, Public Health Director]
Result:	Passed

Voter	Group	Not Present	Yea	Nay	Abstain	Motion	Second
Ivy Taylor	Mayor		x				
Diego Bernal	District 1		x				
	District 2	x					
Rebecca Viagran	District 3		x				x
Rey Saldaña	District 4		x			x	
Shirley Gonzales	District 5		x				
Ray Lopez	District 6	x					
	District 7	x					
Ron Nirenberg	District 8		x				
Joe Krier	District 9		x				
Michael Gallagher	District 10		x				



USER AGREEMENT

Version 02-27-2012

The Centers for Disease Control and Prevention (CDC) works year round to improve and enhance international influenza surveillance efforts and to build global laboratory capacity in preparation for a future pandemic. In September 2008, CDC's Influenza Division contracted with The American Type Culture Collection ("ATCC[®]") to implement the Influenza Reagent Resource (IRR). The IRR, funded by CDC, is a biological reagent repository established to provide free access to influenza virus strains and research reagents. Daily operations of the IRR will be performed by ATCC[®] under the direction of the Influenza Division at the CDC. The IRR resources are available to public health facilities, research institutions, life science companies and other entities, agencies and institutions. In the past, influenza reagents such as virus strains, World Health Organization (WHO) surveillance reagent kits, real time polymerase chain reaction (RT-PCR) kits, and antisera were produced and distributed by the CDC Influenza Division. Now, reagents will be manufactured and distributed by the IRR to increase the availability and accessibility of influenza viruses and reagents for public health purposes.

A Duly Authorized Signatory for the Recipient is required to sign a User Agreement (UA) with ATCC[®]. Each IRR registrant is required to sign an Acknowledgement of User Agreement form. The UA is an agreement that governs the transfer of research materials between two organizations and use of the research materials. Except as otherwise provided herein, the UA is not intended to limit the distribution of biological materials for non-commercial research purposes, with the exception of Pandemic Influenza Preparedness Biological Material (PIP Biological Material) (See http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf). The UA protects the ability of the CDC and ATCC[®] to supply free reagents for the benefit of the public health community. The document defines the duties of the recipients and their institutions, including the responsibility to properly handle, use, and dispose of the materials according to applicable laws and regulations and restrictions provided herein. The UA also protects the rights of all parties involved in the exchange of biomaterials from the original depositor of the material to the end-user.

This UA has been approved in advance by CDC. In order to ensure rapid processing of registration and expeditious distribution of reagents, changes to this Agreement are discouraged.

TERMS AND CONDITIONS

This Influenza Reagent Resource ("IRR") User Agreement (this "Agreement") is between the RECIPIENT and the American Type Culture Collection, a not-for-profit organization having its offices at 10801 University Blvd. Manassas, Virginia 20110, in its capacity as contractor to, and at the direction of and as an agent for, the Centers for Disease Control and Prevention ("CDC"), an agency of the U.S. Department of Health and Human Services ("HHS"). The IRR is a U.S. Government-funded program, which is separate and distinct from other programs at ATCC[®].

DEFINITIONS

COMMERCIAL PURPOSES: For purposes of this Agreement:

- (1) The term COMMERCIAL PURPOSES means the sale, license, lease, export, transfer or other distribution of MATERIAL or MODIFICATIONS to an entity for financial gain or other commercial purposes and/or the use of MATERIAL, or MODIFICATIONS: (a) to provide a service to an entity for financial gain; (b) to produce or manufacture products for general sale or products for use in the manufacture of products ultimately intended for general sale; (c) in connection with ADME (Absorption, Distribution, Metabolism and Excretion) testing; (d) in connection with drug potency or toxicity testing which does not include either screening multiple cell lines for potential inclusion in a screening assay system or screening multiple compounds in a system, in each case for internal research purposes only; (e) in connection with proficiency testing service(s), including but not limited to, providing the service of determining laboratory

performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials in accordance with predetermined conditions; or (f) for research conducted under an agreement wherein a for-profit entity receives rights whether actual or contingent to the results of the research.

- (2) The term COMMERCIAL PURPOSES does NOT include the use of MATERIAL, PIP BIOLOGICAL MATERIAL or MODIFICATIONS for research sponsored by a for-profit organization carried out at a non-profit organization and by the non-profit organization's employees or by any organization for a project funded by the U.S. Government through a grant, cooperative agreement or contract, and only for the purpose(s) of and during the term of that funding agreement. In any event, commercial sale of any product or service based on MATERIAL will require a commercial license from the CONTRIBUTOR.

CONTRIBUTOR: Non-commercial organization and/or individual (including ATCC®) providing ORIGINAL MATERIAL to ATCC® for deposit into the IRR.

IRR PRODUCT: Includes MATERIAL, PIP BIOLOGICAL MATERIAL and THIRD PARTY REAGENTS.

MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES, excludes PIP BIOLOGICAL MATERIAL which is defined below. Also includes, human clinical specimens not containing PIP BIOLOGICAL MATERIAL, seasonal influenza viruses and other non-infectious reagents.

MODIFICATIONS: Substances created by RECIPIENT which contain/incorporate MATERIAL or PIP BIOLOGICAL MATERIAL. Restrictions on the use of MODIFICATIONS in this agreement pertain to ATCC® - or THIRD PARTY REAGENTS only. MODIFICATIONS to PIP BIOLOGICAL MATERIAL must adhere to the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf).

ORIGINAL MATERIAL: The material provided by CONTRIBUTOR to ATCC® for deposit into the IRR.

ORIGINATING LABORATORY: A National Influenza Centre or other authorized laboratory that initially sends PIP biological materials/clinical specimens to other laboratories within the WHO GISRS and to other recipients. (See PIP Framework Section 4.4). http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf

ORIGINATING MEMBER STATE: The Member State where the PIP biological materials/clinical specimens were first collected. (See PIP Framework Sec. 4.4). http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf

PANDEMIC INFLUENZA PREPAREDNESS BIOLOGICAL MATERIALS OR PIP BIOLOGICAL MATERIALS (PIP BIOLOGICAL MATERIAL) defined in the PIP Framework, Section 4 "includes human clinical specimens, virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment. Also included in "PIP biological materials" are RNA extracted from wild-type H5N1 and other human influenza viruses with human pandemic potential and cDNA that encompass the entire coding region of one or more viral genes. http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf).

PRINCIPAL INVESTIGATOR: RECIPIENT's representative receiving and using MATERIAL and/or PIP BIOLOGICAL MATERIAL.

PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT OF USER AGREEMENT: Form signed by the PRINCIPAL INVESTIGATOR acknowledging and agreeing to abide by the terms and conditions of this Agreement.

PROGENY: Unmodified descendant from MATERIAL and/or PIP BIOLOGICAL MATERIAL, such as by way of non-limiting example: virus from virus, cell from cell, or microorganism from microorganism.

RECIPIENT: Organization, institution or legal entity receiving any IRR PRODUCT from the IRR through ATCC®.

SELECT AGENT: Specifically regulated pathogens and toxins as defined in 42 C.F.R. Part 73, including pathogens and toxins regulated by both HHS and USDA as announced in the Federal Register, and listed on the HHS Centers for Disease Control and Prevention web-site at www.cdc.gov.

THIRD PARTY REAGENTS: Commercial reagents (consumable and/or non-propagatable items) which are being distributed by IRR at the request of CDC.

TRANSFeree: An entity receiving any IRR PRODUCT from a RECIPIENT. A Recipient of PIP BIOLOGICAL MATERIALS shall only transfer if the prospective RECIPIENT has concluded an SMTA-2 with the World

Health Organization. (See PIP Framework, Annex 2, Article 4.4).
http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf)

UNMODIFIED DERIVATIVE: Substance created by RECIPIENT that constitutes an unmodified functional subunit or product not changed in form or character and expressed by ORIGINAL MATERIAL. Such non-limiting examples include: subclones of unmodified cell lines, purified or fractionated subsets of ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by CONTRIBUTOR, or monoclonal antibodies secreted by a hybridoma cell line.

RECEIPT; SCOPE OF USE AND TRANSFER

This Agreement is intended to cover IRR PRODUCTS distributed through the IRR to the RECIPIENT and TRANSFEREES. All institutions, organizations, qualified labs and entities shall ensure that handling, storage, use and, when permitted, transfer of MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS, shall at all times be in compliance with all relevant national and international laws, rules and regulations, including those relating to biosafety and biosecurity to the full extent that such laws, rules and regulations are applicable to each party concerned.

RECIPIENT agrees not to claim, infer, or imply governmental endorsement of any research project, any institution or personnel conducting any research project or any resulting product(s).

It is the responsibility of the RECIPIENT to obtain any applicable permits for the IRR PRODUCT and provide copies to ATCC® before the IRR PRODUCT will be shipped.

To receive IRR PRODUCTS which contain SELECT AGENTS, RECIPIENT must obtain necessary permits and written proof of approval from HHS (42 C.F.R. 71, 72, 73) or USDA (7 C.F.R. 331, 9 C.F.R. 121 and 122) to possess SELECT AGENTS, copies of which must be provided to ATCC® before MATERIAL and/or PIP BIOLOGICAL MATERIAL will be shipped. RECIPIENT acknowledges that failure to comply with any laws, regulations or other requirements relating to SELECT AGENTS may result in civil and/or criminal penalties. Transfer of SELECT AGENT MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS to TRANSFEREES is not permissible except as permitted by the appropriate governmental regulatory agencies or authorities and/or the PIP framework http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf.

Recipient agrees that MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS will not be used in humans without prior regulatory approval from the appropriate governmental agencies for such use and the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf). Furthermore, if RECIPIENT has received such regulatory approval, RECIPIENT agrees to conduct the clinical research in accordance with all applicable laws and regulations or otherwise in accordance with U.S. Food and Drug Administration (FDA) Good Clinical Practice (International Conference on Harmonization (ICH) E6: "Good Clinical Practice: Consolidated Guideline"; 62 C.F.R. 25, 691 (1997)).

RECIPIENT acknowledges that MATERIALS and PIP BIOLOGICAL MATERIALS designated as biosafety level 2 or 3 constitute known pathogens or toxins and therefore require appropriate facilities for their use. RECIPIENT also acknowledges that other MATERIALS and PIP BIOLOGICAL MATERIALS not so designated and MODIFICATIONS thereof may be pathogenic under certain conditions.

Biosafety recommendations can be found in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition and available online at <http://www.cdc.gov/od/ohs/biosfty/bmb15/ bmb15toc.htm>.

Execution of additional agreements (such as Standard Material Transfer Agreements (SMTA's)) may be required prior to obtaining PIP BIOLOGICAL MATERIAL. Transfer of non-SELECT AGENT PIP BIOLOGICAL MATERIAL by the RECIPIENT may require the execution of additional agreements (such as MTA's or an SMTA-2 with the World Health Organization).

MATERIAL CONTRIBUTED BY THE CDC

With respect to MATERIAL for which the CDC is the CONTRIBUTOR(as indicated on the IRR product webpage and/or product information sheet originally accompanying such MATERIAL), CDC requires that such MATERIAL be freely transferable (subject to compliance with U.S export control laws with respect to sanctioned countries). RECIPIENT agrees to provide written notice for the transfer of MATERIALS, and to require that its TRANSFEREES provide written notice, of any such transfer to ATCC® within a reasonable period after such transfer.

RECIPIENT and its TRANSFEREES may use such MATERIAL for research and surveillance purposes in the RECIPIENT's and its TRANSFEREES facility, or as allowed by applicable regulations. RECIPIENT may use FDA cleared *in vitro* diagnostic MATERIAL only for diagnostic and surveillance purposes according to the package insert for the *in vitro* diagnostic device and only in RECIPIENT's facility, unless otherwise notified in advance by CDC.

RECIPIENT may use such MATERIAL for research purposes. However, use of MATERIALS for COMMERCIAL PURPOSES is not permitted unless otherwise agreed to in advance by CDC.

Neither CDC nor ATCC® makes representations that the use of the MATERIAL will not infringe any patent or proprietary rights of CONTRIBUTORS or ORIGINATING LABORATORY or ORIGINATING MEMBER STATE.

PIP BIOLOGICAL MATERIAL CONTRIBUTED BY THE CDC

PIP BIOLOGICAL MATERIAL for which the CDC is the CONTRIBUTOR but not the ORIGINATING LABORATORY OR COUNTRY (indicated on the IRR product webpage and/or product information sheet originally accompanying such MATERIAL), must adhere to the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf). Use of PIP BIOLOGICAL MATERIAL for COMMERCIAL PURPOSES must adhere to the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf). Transfers of PIP BIOLOGICAL MATERIAL obtained through the IRR must adhere to U.S export control laws with respect to sanctioned countries. Neither CDC nor ATCC® makes representations that the use of the PIP BIOLOGICAL MATERIAL will not infringe any patent or proprietary rights of CONTRIBUTORS, ORIGINATING LABORATORY or ORIGINATING MEMBER STATE.

MATERIAL CONTRIBUTED BY ATCC® AND THIRD PARTIES, NOT TO INCLUDE CDC-CONTRIBUTED MATERIAL

RECIPIENT may not transfer MATERIAL for which ATCC® is the CONTRIBUTOR or THIRD PARTY REAGENTS (as indicated on the certificate of analysis and/or product information sheet originally accompanying such MATERIAL) and MODIFICATIONS therefrom without prior written consent of ATCC® and/or CONTRIBUTOR.

Use of such MATERIAL and MODIFICATIONS therefrom by RECIPIENT is subject to certain restrictions specified in the product information supplied with such MATERIAL. RECIPIENT agrees to use such MATERIAL and MODIFICATIONS only for the purpose specified in the applicable product information document.

RECIPIENT may use such MATERIAL and MODIFICATIONS for research purposes only and not for COMMERCIAL PURPOSES unless otherwise agreed to in advance by ATCC® and/or CONTRIBUTOR, as applicable. Any application for COMMERCIAL PURPOSES may require a license from parties claiming ownership. Neither CDC nor ATCC® nor CONTRIBUTOR makes any representations that the use of the MATERIAL will not infringe any patent or proprietary rights of CONTRIBUTORS.

On expiration or earlier termination of this Agreement, RECIPIENT agrees that any of such MATERIAL and MODIFICATIONS remaining will be destroyed (unless requested by ATCC® to return such remaining MATERIAL) and to provide written proof thereof to ATCC® no later than thirty (30) days from the date of expiration or termination.

INVENTIONS AND PATENTS

No RECIPIENT or TRANSFEREE shall seek intellectual property rights on IRR PRODUCTS, including PIP BIOLOGICAL MATERIALS. This provision does not prohibit the filing of patent application(s) claiming inventions made

by RECIPIENT through the use of MATERIAL, PIP BIOLOGICAL MATERIAL, MODIFICATIONS or THIRD PARTY REAGENTS, provided that no patent applications shall be made on PIP Biological Materials.

TRADEMARKS

Nothing in this Agreement shall be construed to grant any license or use rights with respect to ATCC®'s rights, title and interests in and to trademarks registered or owned by ATCC® or the U.S. Government or any and all ATCC® catalog numbers or ATCC®-specific designations of biological materials sold by ATCC®.

CONFIDENTIALITY; PUBLICATIONS

RECIPIENT agrees to treat in confidence any of ATCC®'s, the IRR's or CONTRIBUTOR's information about MATERIAL that is by its nature reasonably expected to be confidential or proprietary, except for information that (i) was previously known to RECIPIENT, (ii) that is or becomes publicly available other than as a result of a breach of a confidentiality obligation, (iii) that is independently developed by RECIPIENT without the aid or benefit of such disclosed information, or (iv) that is required to be disclosed by a court of competent jurisdiction. Notwithstanding the above, the RECIPIENT shall respond to requests for records pertaining to this Agreement in compliance with the Texas Public Information Act.

RECIPIENT may publish or otherwise publicly disclose the results of the work with MATERIAL or MODIFICATIONS but if RECIPIENT received confidential information from CDC, ATCC® or CONTRIBUTOR, then only after the source of the confidential information has had ninety (90) days to review the proposed disclosure to determine whether it includes any Confidential information, except when a shortened time period under court order of the Freedom of Information Act, 5 U.S.C. § 552, pertains. RECIPIENT agrees to provide a reference of all publications relating to ORIGINAL MATERIAL and MODIFICATIONS to the IRR.

Acknowledgment of the use of PIP BIOLOGICAL MATERIAL should adhere to the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf). RECIPIENT agrees that ATCC® may inform CONTRIBUTOR of RECIPIENT'S identity if required to do so by law, by CONTRIBUTOR, or if MATERIAL or PIP BIOLOGICAL MATERIAL is subject to an issued patent.

WARRANTY; WARRANTY DISCLAIMER

Any expiration date specified on shipment documentation for MATERIAL and PIP BIOLOGICAL MATERIAL states the expected remaining useful life, but does not constitute a warranty or extend any applicable warranty period. MATERIAL and PIP BIOLOGICAL MATERIAL and any technical information and assistance provided by ATCC® are provided "as is", without warranties of any kind, express or implied, including, but not limited to any implied warranties of merchantability, fitness for a particular purpose, typicality, safety, accuracy and non-infringement.

SAFETY; COMPLIANCE WITH LAWS

Except to the extent prohibited by law, RECIPIENT assumes all risks and responsibility in connection with RECIPIENT's (or its TRANSFEREES, if permitted) receipt, handling, storage, disposal, internal transfer and use of MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS including without limitation taking all appropriate safety and handling precautions to minimize health or environmental risk, as well as for any adverse events resulting from RECIPIENT's (or its TRANSFEREES) violation of the security requirements or unauthorized dissemination of MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS. RECIPIENT is solely responsible for its and its TRANSFEREES compliance with all applicable foreign and domestic, federal, state and local statutes, ordinances, regulations and guidelines, including U.S. export control laws in regards to U.S. sanctioned countries.

RECIPIENT hereby certifies that RECIPIENT shall (1) ensure that only qualified personnel work with MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS in proper facilities; (2) provide sufficient internal security to assure access to MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS only by those individuals authorized to work with them; (3) not transfer, export, resell, or otherwise dispose of any MATERIAL, PIP BIOLOGICAL MATERIAL or MODIFICATIONS to any TRANSFEREE under any circumstances unless permitted by CDC and/or the PIP framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf), or as explicitly provided for within this

Agreement; (4) ensure that there is compliance with all domestic and international regulations impacting the transfer of the MATERIALS and PIP BIOLOGICAL MATERIAL including with respect to sanctioned countries under U.S. export control laws; (5) ensure that there is compliance with the PIP framework http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf) for any transfers of PIP BIOLOGICAL MATERIAL; (6) not permit access to MATERIAL, PIP BIOLOGICAL MATERIAL or MODIFICATIONS by foreign entities or individuals when to do so would be in violation of export control laws; (7) comply with all applicable federal, state, or local laws and regulations pertaining to MATERIAL, PIP BIOLOGICAL MATERIAL or MODIFICATIONS or their handling, storage, use, transportation; and (8) with respect to ATCC® - contributed MATERIAL or MODIFICATIONS (but not CDC contributed MATERIAL, PIP BIOLOGICAL MATERIAL or MODIFICATIONS), unless requested otherwise by ATCC®, destroy all MATERIAL and MODIFICATIONS according to accepted practices for destruction of biohazardous material upon completion of work or expiration or termination of this Agreement, which ever occurs first.

INDEMNIFICATION

Except to the extent prohibited by law, RECIPIENT assumes all risks and responsibility in connection with RECIPIENT's receipt, handling, storage, disposal, and use of MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS including without limitation taking all appropriate safety and handling precautions to minimize health or environmental risk, as well as for any adverse events resulting from RECIPIENT's violation of the security requirements or unauthorized dissemination of MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS. RECIPIENT is solely responsible for its compliance with all applicable foreign and domestic, federal state and local statutes, ordinances, regulations and guidelines.

LIMITATION OF LIABILITY

In no event will ATCC®, the U.S. government or contributors be liable for any special, incidental or consequential damages of any kind in connection with or arising out of this agreement, MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS (whether in contract, tort, negligence, strict liability, statute or otherwise) even if such entity has been advised of the possibility of such damages.

RECIPIENT agrees that the limitations of liability set forth in this Agreement shall apply even if a limited remedy provided hereunder fails of its essential purpose.

SHIPPING

IRR PRODUCTS will be packaged and shipped in accordance with applicable laws and regulations governing transport of biological products. RECIPIENT is responsible for ensuring that all permits required for RECIPIENT to receive its order are obtained and that sufficient proof of such permits is provided to ATCC®. ATCC® will notify RECIPIENT when orders are submitted without the necessary permits, and RECIPIENT will have a six (6) month period after such notification to supply proof of the necessary permit(s) before an order will be cancelled. Each IRR PRODUCT is shipped Free On Board (FOB) point of shipment, via carrier of ATCC®'s choice or recommendation of RECIPIENT upon approval by CDC.

RECIPIENT agrees that PRINCIPAL INVESTIGATOR shall (i) have executed and returned a PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT OF USER AGREEMENT to ATCC®, and (ii) shall inform ATCC® in writing of the date of receipt within five (5) working days of receiving an IRR PRODUCT undamaged or within twenty-four (24) hours of receipt or expected receipt if an IRR PRODUCT is damaged or lost. If an IRR PRODUCT is damaged or lost during shipment, ATCC® will replace such IRR PRODUCT, provided RECIPIENT has reported lost or damaged shipments to the applicable carrier and notified the IRR Customer Service Department (contact@influenzareagentresource.org)

DURATION OF AGREEMENT

This Agreement will be effective in perpetuity after the date of the last signature below unless and until terminated by ATCC®. RECIPIENT understands that ATCC® may terminate this Agreement at any time with written notice to RECIPIENT and that certain provisions may survive such termination as provided by ATCC®. Alternatively, the

RECIPIENT may at any time terminate the User Agreement (other than with respect to any RECIPIENT or TRANSFEREE obligations that survive termination), and must destroy all ATCC® MATERIAL or THIRD PARTY REAGENTS.

MISCELLANEOUS

RECIPIENT may not assign or otherwise transfer this Agreement or any rights or obligations under this Agreement, whether by operation of law or otherwise. Any attempted assignment or transfer will be void and of no force or effect. This IRR User Agreement and all documents incorporated herein by reference constitute the entire agreement between ATCC® and RECIPIENT with respect to MATERIAL, PIP BIOLOGICAL MATERIAL and MODIFICATIONS and supersede all previous agreements or representations.

RECIPIENT agrees to comply with any additional requirements of the CONTRIBUTOR as specified for MATERIAL, PIP BIOLOGICAL MATERIAL and/or MODIFICATIONS in the IRR web catalog.

SIGNATURES ON NEXT PAGE

THE UNDERSIGNED SIGNATORY OF RECIPIENT CERTIFIES THAT HE OR SHE HAS THE AUTHORITY TO MAKE THE ABOVE CERTIFICATIONS AND REPRESENTATIONS ON BEHALF OF RECIPIENT AND FURTHER WARRANTS THAT HE OR SHE IS LEGALLY AUTHORIZED TO ENTER INTO THIS BINDING AGREEMENT ON BEHALF OF RECIPIENT.

READ AND UNDERSTOOD BY DULY AUTHORIZED SIGNATORY FOR RECIPIENT

DULY AUTHORIZED SIGNATORY FOR RECIPIENT

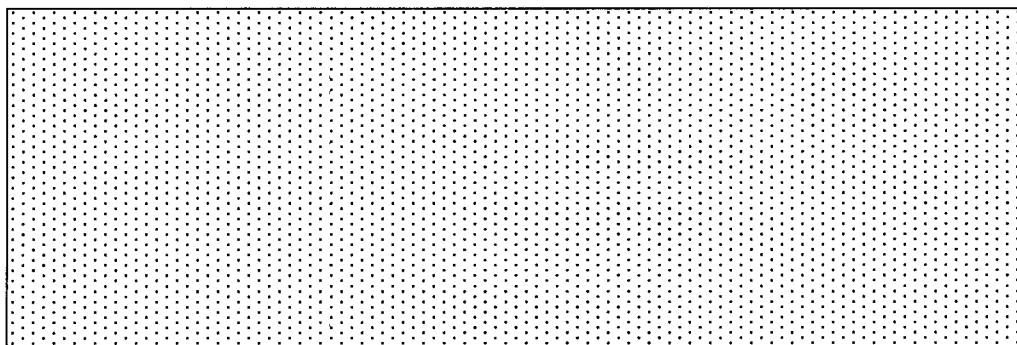
Printed Name _____ Position Description _____

Phone Number _____ Email _____

Institution/Entity _____

Address _____

Signature _____ Date _____



The completed and signed User Agreement can be sent via email, fax or postal mail. Please send documents to:

Email: contact@influenzareagentresource.org

Fax: (703) 334-2945

IRR

Attn: Customer Service

American Type Culture Collection

10801 University Blvd.

Manassas, VA 20110-2209 USA

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