

April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. *Frequency of*

*Response:* Once per CVD event. *Affected Public:* Individuals. *Types of Respondents:* Physicians and selected proxies of individuals recruited for MESA. The annual reporting burden is as follows: *Estimated Number of*

*Respondents:* 550; *Estimated Number of Responses per Respondent:* 1.0; and *Estimated Total Annual Burden Hours Requested:* 36.7.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physicians .....	250	1.0	0.20	16.7
Participant proxies .....	300	1.0	0.20	20
Total .....	550	1.0	0.20	36.7

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Jean Olson, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD 20892-7936, or call non-toll-free number 301-435-0397, or e-mail your request, including your address to: [olsonj@nhlbi.nih.gov](mailto:olsonj@nhlbi.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 9, 2007.

**Michael Lauer,**

Chief, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Approved: August 9, 2007.

**Suzanne Freeman,**

NHLBI Project Clearance Officer, National Institutes of Health.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Prophylactic Vaccines and Therapeutic Monoclonal Antibodies Against Influenza**

*Description of Technology:* This technology describes development of H5N1 influenza vaccine candidates in which mutations have been introduced to increase affinity of the hemagglutinin (HA) for the sialic acid receptor found in humans, which have a different sialic acid linkage than the corresponding avian receptor. These mutations could therefore result in a higher immune response in vaccines, producing a more robust response than other H5N1 vaccine candidates that retain their

avian receptor preferences. These mutations also changed antibody-sensitivity of the vaccine candidates. The H5 modifications can be expressed from DNA or adenoviral vectors, or the proteins themselves can be administered. Additionally, these mutated HAs can be used to develop therapeutic monoclonal antibodies. The technology describes three (3) unique monoclonal antibodies that react with wild-type H5, wild-type H5 and mutant HA equivalently, and the mutant HA, respectively.

*Applications:* Prophylactic influenza vaccine; Therapeutic antibodies.

*Inventors:* Gary J. Nabel *et al.* (VRC/NIAID).

*Patent Status:* U.S. Patent Application No. 60/850,761 filed 10 Oct 2006 (HHS Reference No. E-306-2006/0-US-01).

U.S. Patent Application No. 60/860,301 filed 20 Nov 2006 (HHS Reference No. E-306-2006/1-US-01).

U.S. Patent Application No. 60/920,874 filed 30 Mar 2007 (HHS Reference No. E-306-2006/2-US-01).

U.S. Patent Application No. 60/921,669 filed 02 Apr 2007 (HHS Reference No. E-306-2006/3-US-01).

*Development Status:* Animal (mouse) data available.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Susan Ano, Ph.D.; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

**Antiviral Compounds With Broad Neutralization Capabilities**

*Description of Technology:* The NIH is pleased to announce as available for licensing a technology that provides for novel antiviral compounds effective against a broad spectrum of viruses. The compounds utilize soluble phospholipases, exemplified by PLA<sub>2</sub>-X and others, either alone or as a fusion protein with a viral binding polypeptide. These compositions are able to inactivate viruses through enzymatic degradation of the viral membrane without affecting target cells

of infection. The potential broad application of these compounds could address a significant health need for effective antivirals.

**Applications:** This technology provides compositions and methods for the treatment of viral infection and has human and veterinary applications.

**Advantages:** The compounds described by the current technology are not necessarily specific for a type of virus or viral strain like many currently available antiviral compounds, and therefore have broad therapeutic antiviral applications. Further, virions resistant to damage by antibody and complement have been shown to be lysed by compounds of the invention suggesting antiviral surveillance independent of a humoral immune response.

**Development Status:** Proof of concept in vitro studies using human cells have shown antiviral activity with viruses pseudotyped with envelope proteins from Ebola, HIV, Marburg and MoMuLV.

**Inventors:** Gary Nabel and Jae-Ouk Kim (VRC/NIAD).

**Publication:** J-O Kim *et al.* Lysis of human immunodeficiency virus type 1 by a specific secreted human phospholipase A<sub>2</sub>. *J Virol.* 2007 Feb;81(3):1444–1450.

**Patent Status:** PCT Application No. PCT/US2007/004471 filed 21 Feb 2007 (HHS Reference No. E-013-2006/1-PCT-01).

**Licensing Status:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Susan Ano, Ph.D.; 301/435-5515; [AnoS@mail.nih.gov](mailto:AnoS@mail.nih.gov)

### Design of Multi-Functional RNA Nanoparticles and Nanotubes

**Description of Invention:** The characteristic function of nanoparticles is their ability to deliver drug across biological barriers to the target site while protecting the drugs from the biological environment until they reach the target site. The present invention provides polyvalent RNA nanostructures comprising RNA I inverse (RNA Ii) or RNA II inverse (RNA Iii) like motifs that have multiple positions available for conjugation of therapeutic, diagnostic or delivery agents. The nanoparticles of the invention do not induce significant immune response by themselves and are smaller than currently available nanoparticles and therefore allow for increased efficiency of administration. The nanoparticles of this invention have the ability to deliver one or more different therapeutic agents in a single particle. Further, the RNA nanoparticles are also capable of self-assembly into

nanotubes of various shapes which offer potentially broad uses in medical implants, gene therapy, nanocircuits, scaffolds and medical testing.

**Applications:**

1. Use as diagnostic tool.
2. Use as drug delivery composition to treat various diseases or conditions.
3. Use in screening or identifying potential chemotherapeutic agents.
4. Use in riboswitch aptamers, ribozymes or beacons.
5. Use in nanocircuits, medical implants, gene therapy, scaffolds and medical testing.

**Market:** Broad application in various fields, such as therapeutics, drug delivery, diagnostics, provides a wide market potential.

**Development Status:** Early stage.

**Inventors:** Bruce A. Shapiro and Yaroslava G. Yingling (NCI).

**Publication:** YG Yingling and BA Shapiro. Computational Design of an RNA Hexagonal Nanoring and an RNA Nanotube. *Nano Lett.* 2007 Jul 6. Epub ahead of print, doi 10.1021/nl070984r.

**Patent Status:** U.S. Provisional Application No. 60/810,283 filed 02 Jun 2006 (HHS Reference No. E-233-2006/0-US-01).

U.S. Provisional Application No. 60/918,181 filed 14 Mar 2007 (HHS Reference No. E-233-2006/1-US-01).

**Licensing Status:** Available for exclusive and non-exclusive licensing.

**Licensing Contact:** Robert M. Joynes J.D., M.S.; 301/594-6565; [joynesr@mail.nih.gov](mailto:joynesr@mail.nih.gov).

**Collaborative Research Opportunity:** The National Cancer Institute's Nanobiology Program (<http://www-lecb.ncifcrf.gov/bshapiro/index.html>) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize RNA nanostructures. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

### Methods for Preparing Complex Multivalent Immunogenic Conjugates

**Description of Technology:** Claimed in this application are novel methods for preparing complex multivalent immunogenic conjugates and conjugate vaccines. The multivalent conjugates and conjugate vaccines are synthesized by conjugating mixtures of more than one polysaccharide at a desired ratio of the component polysaccharides to at least one carrier protein using hydrazide chemistry. Because of the high efficiency of hydrazide chemistry in conjugation, the polysaccharides are effectively conjugated to the carrier protein(s) so that the resulting complex

synthesized vaccine conjugate products, without requiring tedious and complicated purification procedures such as chromatography and/or ammonium sulfate precipitation, are efficacious in inducing antibodies in mice against each component polysaccharide. The methods claimed in this application simplify the preparation of multivalent conjugate vaccines by utilizing simultaneous conjugation reactions in a single reaction mixture or batch that includes at least two immunogenic-distinct polysaccharides. This single-batch simultaneous reaction eliminates the need for multiple parallel synthesis processes for each polysaccharide vaccine conjugate component as employed in conventional methods for making multivalent conjugate vaccines.

**Application:** Cost effective and efficient manufacturing of conjugate vaccines.

**Inventors:** Che-Hung Robert Lee (CBER/FDA).

**Patent Status:** PCT Application No. PCT/US2007/006627 filed 16 Mar 2007 (HHS Reference No. E-085-2005/0-PCT-02).

**Licensing Status:** Available for exclusive or non-exclusive licensing. The technology is not available for licensing in the field of use of multivalent meningitis vaccines.

**Licensing Contact:** Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

Dated: August 13, 2007.

**Steven M. Ferguson,**

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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